Mycobacteriology

Acid-Fast (Mycobacteria) Culture and Smear

Synonyms: AFB Test

Useful For: Stopping the spread of a Communicable disease by quickly identifying patients with active tuberculosis using positive smears. Primary step for isolating and identifying all species of Mycobacteria from clinical specimens. Provides the isolate needed to test for antibiotic susceptibilities.

Request Form: Bact. 68

Specimen: First morning sputum (not saliva), fasting gastric aspirate, induced sputum, whole blood, tissue, biopsy, bronchial aspirate, urine, skin, GSF, bone marrow, body fluid, stool.

Volume: 5ml sputum or respiratory aspirate, 5ml gastric aspirate, 10ml whole blood, 2 CM^3 tissue, 50ml urine, 5ml CSF, 5cc bone marrow, 50ml body fluid, 10ml stool, scraping or biopsy of skin.

Container: Sterile screw-capped container (glass jar or vial) in a double wall mailer - (metal inner with cardboard outer).

Collection: Requires Aseptic technique and varies with specimen type.

Storage Instructions: Refrigerate: Deliver to testing site as quickly as possible for best results.

Causes for Rejection: Improper (non-sterile) container used. Specimen broken or leaked in transit. Insufficient quantity of specimen. No patient identification with specimen. Immediate notification will be made and additional specimens will be requested.

Interpretation: Presence of AFB on smears is reported based upon the number of bacilli seen. Subsequent viable AFB isolates are identified to the species level and antibiotic susceptibility testing is done. No AFB on smear and no growth in Bactec 12B vials, in MGIT tubes and on 7H11 agar plates is considered a negative test.

Method: Direct smear examinations are done using the auramine - rhodamine stain. The broth based Bactec and MGIT systems are used along with conventional 7H11 agar plates for isolation. Use of the Bactec 460 system reduces incubation time to four weeks.

Normals/Reference Interval: No acid fast organisms recovered.

Cautions or Limitations: Requires sterile technique in a Level III BioSafety Laboratory, staffed by experienced Mycobacteriologists. Success rate is higher if multiple (3-6) specimens are submitted. Proper specimen selection, collection and processing provides better results.

Reference:

1. Pierce M. S.O.P. Mycobacteriology Laboratory Manual - N.J. State Department of Health - 1995.
2. Kent, P.T., Kubica, G.P. Public Health Microbiology, A Guide for the Level III Laboratory 1985. Center for Disease Control.
3. Murray, P.R. et. al. Manual of Clinical Microbiology - 6th ed A5M Press 1995 Chapter 31 (400-437)
4. ASTPHLD, C.D.C. Mycobacterium tuberculosis: Assessing your Laboratory March 1995.

Charge: $30 for each specimen.

Bacteriology

Antibiotic Screening - Dairy Products

Note: Enforcement of State and Federal Regulations

Synonyms: Inhibitory substances; B-lactams

Useful For: Screen dairy products for Beta-Lactam residues and other inhibitory substances.

Request Form: Bact. 10

Specimen: Dairy products

Volume: 100 ml

Container: Original sealed container or sterile single service containers.

Collection: By certified rating officers.

Storage Instructions: Samples must be transported and submitted at 0-4.4°C.

Causes for Rejection:

1. Leaking or unsterile container.
2. Samples not transported and received at 0-4.4°C.
3. Samples exceeding the time limit.
4. No temperature control.

Interpretation: Presence of B-lactams or other inhibitory substances are indicative of an adulterated product and are rejected.

Method: Disk and receptor assay.

Normals/reference Interval: Adhere to established tolerance levels for the target antibiotics.

Cautions or Limitations: Confirm all "screening" positive samples.

Reference: Standard Methods For the Examination of Dairy Products.

Charge: N/A-Enforcement only.

Special Immunology

Aspergillus Serology

Synonyms: Aspergillus Immunodiffusion, Aspergillus ID, Aspergillus Antibodies Qualitative

Useful For: Detection of antibodies in persons having aspergillosis, primarily allergic bronchopulmonary disease or fungus ball.

Request Form: SRD-1

Specimen: Serum

Volume: 3 ml

Container: Red top tube

Collection: Collect aseptically with patient in fasting state.

Storage Instructions: Refrigerate

Causes for Rejection: Inadequate labeling, excessive hemolysis, lipemic serum, gross contamination of the specimen.

Interpretation: One or more precipitin bands is indicative of infection, colonization or allergy due to an Aspergillus species. The greater the number of precipitin bands, the greater the likelihood of either a fungus ball or invasive aspergillosis.

Method: Immunodiffusion (ID)

Normals/Reference Interval: Negative. No precipitin bands.

Cautions or Limitations: Approximately 20% of patients with allergic bronchopulmonary aspergillosis will be negative in the ID test. IgM antibodies frequently predominate in patients with early, primary infection (first 3-6 weeks), and diffuse slowly in the gel due to their large molecular size. A negative test does not exclude an aspergillosis infection.

Reference:

1. Kaufman L and Reiss E, "Serodiagnosis of Fungal Diseases", Manual of Clinical Laboratory Immunology, 4th ed. vol, 2, chapter 78, Rose NR, Conway de Macario E, Fahey JL, et al, eds, Washington, DC: American Society for Microbiology, 1992, 506-28.
2. Kaufman L. 1973. Value of Immunodiffusion Tests in the Diagnosis of Systemic Mycotic Diseases. Ann. Clin. Labs. Sci. 3:141-146.

3. Package Insert Immuno-Mycologic, Inc. ID Kit.

Charge: None

Bacteriology

Botulism, Toxin Studies

Synonyms: Clostridium botulinum diagnostic procedure, Infant botulism, Toxin identification

Useful For: Diagnosis of Botulism. Prior approval from the NJ Division of Epidemiology (609-588-7500) is required before submission of specimens.

Request Form: Hospital laboratory form

Specimen: Serum, stool, vomitus, gastric washings, food products implicated in intoxications.

Volume: No less than 3-5ml of serum, 10-50grams of stool, vomitus, etc.

Container: Sterile wide mouth, leak proof screw-cap jar, red top tube.

Collection: Special Instructions: Pooled stool specimens are acceptable in cases of infant botulism. Stool is the specimen of choice in these cases.

Storage Instructions: Keep all specimens refrigerated at 4C except for unopened food specimens.

Causes for Rejection: Results of tests of insufficient quantities will be qualified.

Interpretation: Toxin types A, B, E, and F are the principal causes of botulism in humans. The diagnosis of botulism can be confirmed in about one of three botulism patients by demonstrating botulinal toxin in serum. Detection of toxin in the patient's stool is equally effective. Toxin has never been found by the CDC in any serum or stool specimen from persons without botulism.

Method: Toxin neutralization test in mice.

Normals/Reference Interval: No toxin found.

Cautions or Limitations: Patient specimens must be collected before administration of therapeutic antitoxin. The toxin from C. botulinum binds almost irreversibly to individual nerve terminals; thus serum specimens may yield false-negative results.

Reference: Clostridium Botulinum Monovalent and Polyvalent Antitoxins, us Dept. of Health and Human Services, Public Health Service, Atlanta, Ga. 30333 Oct 1977 revised Oct 1980.

Charge: No charge

Special Immunology

Brucellosis Agglutinins

Synonyms: Tube test Brucella Antibodies, tube agglutination test

Useful For: Support the clinical diagnosis of Brucellosis.

Request Form: SRD-1

Specimen: Serum

Volume: 3 ml

Container: Red top tube

Collection: A convalescent sample is recommended to be drawn 10-14 days apart.

Storage Instructions: Refrigerate

Causes for Rejection: Excessive hemolysis, lipemic serum, gross contamination of specimen

Interpretation: Titers $\geq$ 1:80, on a single specimen are considered significant. A four-fold rise in titer is indicative of an active infection.

Method: Tube agglutination

Normals/Reference Interval: Negative. Less than a four-fold rise in titer on paired sera drawn 10-14 days apart.

Interpretation: ID - One or more predipitin bands is presumptive evidence for systemic candidiasis or colonization

Cautions or Limitations: Previous vaccination may have an effect on the titer. Will not detect antibodies in patients having infection with Brucella canis.

Reference:

1. Gazapo E, Gonzalez-Lahoz J, Subiza JL, et al, "Changes in IgM and IgG Antibody Concentrations in Brucellosis Over Time, Importance for Diagnosis and Follow-Up", J. Infect. Dis, 1989, 159(6):219-25.
2. Hausler WJ, Jr, Moyer NP, Holcomb LA: Brucella. In Manual of Clinical Microbiology - Washington, DC, American Society of Microbiology, 1991.

Charge: None

Bacteriology

C. perfringens toxin studies

Synonyms: C. perfringens enterotoxin type A test

Useful For: Determination of cause of gastroenteritis with short onset times. Prior approval by Division of Epidemiology (609-588-7500) is required before submission of specimens.

Request Form: Bact. 25

Specimen: Stool collected as soon as possible after onset of symptoms.

Volume: 25 to 50 grams

Container: Blue labeled container

Collection: Collect specimens in sterile, leakproof containers with preservative of Buffered Glycerol Saline, C&S or other commercial stool transport and deliver at 4C.

Storage Instructions: Maintain specimens in the refrigerator.

Causes for Rejection: Negative specimens will be qualified if specimen is delayed in transit.

Interpretation: Direct enterotoxin detection in stool is the most reliable method. Food poisoning can result from eating foods contaminated with C. perfringens. The ingested cells multiply in the patient's intestines and produce spores. The production of enterotoxin is associated with this spore forming process. It is, therefore, important to detect the enterotoxin in fecal specimens obtained from the patient.

Method: Reversed passive latex agglutination (RPLA)

Normals/Reference Interval: Enterotoxin not found.

Cautions or Limitations: Sensitivity of the test is approximately 2ng/ml. Enterotoxin present at concentrations lower than this will give negative results. No other types of enterotoxins of C. perfringens will be detected.

Reference: Oxoid Toxin Detection Kits: PET-RPLA, Unipath Limited, Hampshire, England, April 1990.

Charge: No charge

Special Immunology

Candidiasis Serology

Synonyms: Candida Antibody, Candida Antigen

Useful For: Aid in the diagnosis of systemic candidiasis.

Request Form: SRD-1

Specimen: Serum

Volume: 3 ml

Container: Red top tube

Collection: Aseptic, paired sera is recommended.

Storage Instructions: Refrigerate

Causes for Rejection: Grossly contaminated specimen.

and should be evaluated in light of clinical data. An increase in numbers of bands is indicative of increase in severity of infection.
LA - Titers of ≥ 1:2 are indicative of disseminated disease.
Method: Immunodiffusion (ID) and Latex Agglutination (LA)
Normals/Reference Interval: Negative
Cautions or Limitations: Cross reactions occur in cases of cryptococcosis and tuberculosis with the latex agglutination. Negative results do not rule out candidiasis.
Reference:
1. Escuro RS, Jacobs M, Gerson SL, et al, "Prospective Evaluation of a Candida Antigen Detection for Invasive Candidiasis in Immunocompromised Adult Patients with Cancer", Am J Med, 1989, 87(6):621-7.
2. Hayette MP, Strecker G, Faille C, et al, "Presence of Human Antibodies Reacting with Candida Albicans O-Linked Oligomannosides Revealed by Using an Enzyme-Linked Immunosorbent Assay and Neoglycolipids", J Clin Microbiology, 1992, 30(2): 411-7.
Charge: None

Bacteriology
Chlamydia EIA
Synonyms: Enzyme Immunoassay for Chlamydia, Microtrak II Chlamydia EIA
Useful For: Screening genital specimens for Chlamydia. Prior approval of the Sexually Transmitted Disease Control Program (609-588-7526) is required before submission of specimens.
Request Form: Bact. 70
Specimen: Cervical or urethral swab
Volume:
Container: Chlamydia Specimen Collection Kit
Collection: Cervical: Wipe exocervix with large swab to remove excess mucus. Insert large or small swab onto endocervical canal until most of tip is not visible. Rotate the swab for 5-10 secs. Withdraw swab without touching any vaginal surfaces. Urethral: Patient should not urinate for an hour prior to sampling. Insert small swab 2-4 cm into urethra. Rotate swab and withdraw.
Follow instructions supplied in Collection Kit.
Storage Instructions: Transport and store specimens at 2-25C.
Causes for Rejection: Use of swabs not supplied with collection kit, culture of rectal, throat or unconcentrated urine specimens.
Interpretation: Test results should be interpreted in conjunction with the patient's clinical presentation and other diagnostic test results. Positive results in low-prevalence population should be interpreted with caution.
Method: Enzyme Immunoassay
Normals/Reference Interval: Chlamydia not found.
Cautions or Limitations: TEST SHOULD NOT BE USED FOR EVALUATION OF SEXUAL ABUSE. Antibody used in this test does not differentiate between species of Chlamydia. Positive results should be considered to be presumptive unless confirmed by blocking assay.
Reference: Behring Diagnostics (Syva Company), Microtrak(R) II Chlamydia EIA, San Jose, California, 1994.
Charge: No charge for family planning patients less than or equal to 28 years old and patients seen at exempt clinics. All others $4.

Special Immunology
Cryptococcus Serology
Synonyms: Cryptococcus Antibody, Cryptococcus Antigen, Cryptococcosis
Useful For: Useful in the diagnosis and prognosis of cryptococcal infections.
Request Form: SRD-1
Specimen: Serum, CSF
Volume: 3 ml
Container: Red top tube, sterile CSF tube
Collection: Aseptic, paired sera is recommended.
Storage Instructions: Refrigerate
Causes for Rejection: Gross contamination of the specimens.
Interpretation: LA - Titers of ≤ 1:4 are suggestive and additional specimens should be submitted. Titers of ≥ 1:8 are highly suggestive of active infection.
TA - Titers of ≥ 1:2 indicate current or recent infection.
Method: Latex Agglutination (LA) and Tube Agglutination (TA)
Normals/Reference Interval: Negative
Cautions or Limitations: A negative TA result does not rule out infection as an antibody response may be masked by circulating antigen. False-positive results may be seen in patients with rheumatoid arthritis.
Reference: Kaufman L and Reiss E, "Serodiagnosis of fungal diseases", Manual of Clinical Laboratory Immunology, 4th ed. Vol 2, Chapter 78, Rose NR, Conway de Macario E, Fahey JL, et al, eds. Washington, DC: American Society for Microbiology, 1992, 517-19.
Charge: None

Bacteriology
Culture Identification
Synonyms: Identification of bacteria
Useful For: Confirmation of unusual isolates, identification of organism previously uncharacterized, identification of organisms unable to be identified by rapid systems.
Request Form: Bact. 109
Specimen: Pure culture on appropriate medium.
Volume: Viable colonies
Container: Agar slant with a screw-cap mailed in containers that conform to US Postal regulations.
Collection: Isolate organisms from various patient specimens. Grow in pure culture on appropriate media.
Storage Instructions: Maintain specimen at room temperature.
Causes for Rejection: Culture broken or destroyed in transit will not be processed.
Interpretation: Organisms will be characterized into Genus and species according to standard scientific nomenclature.
Method: Standard identification appropriate to the culture submitted.
Normals/Reference Interval: Does not apply.
Cautions or Limitations: Organisms which cannot be identified using methods available will be sent to the Centers for Disease Control.
Reference: Jacobs D., Demott W., Laboratory Test Handbook 3rd edition, Hudson, Ohio, Lexi-Comp Inc., 1994.
Charge: $30

Viral Serology
Cytomegalo Virus - FIA
Synonyms: CMV, fluorometric immunoassay, cytomegalic inclusion disease
Useful For: Determining the CMV specific antibodies in serum or plasma. May be used to assess immune status with a single specimen.
Request Form: SRD-1

Specimen: Serum or plasma
Volume: 2-5ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of > 1:20 is considered reactive.
Method: Fluorometric immunoassay
Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.
Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Viral Serology

Cytomegalo Virus IgM - FIA

Synonyms: CMV, IgM fluorometric immunoassay, cytomegalic inclusion disease
Useful For: Determining the CMV IgM specific antibodies in serum or plasma. May be used as a diagnostic assay with a single specimen.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 2-5ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of > 1:15 is considered indicative of a current infection.
Method: Fluorometric immunoassay
Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.
Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Diagnostic Virology

Cytomegalovirus Isolation

Synonyms: CMV, Cytomegalic inclusion disease
Useful For: Determining the etiology of a suspected viral infection.
Request Form: SRD-1
Specimen: Urine, saliva, stools, cervical secretions and autopsy tissue.
Volume: Urine and saliva 1 - 5ml. Three consecutive stools (size of walnut). Cervical swab in 2.0ml, 0.5% gelatin saline solution or culturette.
Container: Urine, saliva and stools in sterile, dry screw cap jar. Swabs in sterile screw cap tubes.
Collection: Postmortem tissue should be collected within 24hrs of death.
Storage Instructions: Specimens should be stored at 4°C and delivered to the laboratory within 24hrs of collection.
Causes for Rejection: Breakage, leakage of specimen containers or obvious bacterial contamination will be cause for rejection.
Interpretation: The presence of a slowly progressive, focal, cytopathogenic effect (CPE) are indicative of viral isolation.
Method: Inoculation in tissue culture.
Normals/Reference Interval: Failure to see CPE in tissue culture after one 4 - 6 week incubation period.
Cautions or Limitations: Failure to isolate a virus does not rule out the possibility of a viral infection.
Reference: Lennette, E.H. and N.J. Schmidt."Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections", 6th Edition, American Public Health Association, Washington, DC.
Charge: None

Bacteriology

Direct Microscopic Somatic Cell Count - Dairy

Note: Enforcement of State and Federal Regulations
Synonyms: DMSCC, Somatic Cell Count
Useful For: Enumerating somatic cells in raw milk.
Request Form: Bact. 10
Specimen: Raw milk
Volume: 100 ml
Container: Sterile single service container.
Collection: By certified rating officers.
Storage Instructions: Samples must be transported and submitted at 0-4.4°C.
Causes for Rejection:
1. Leaking or unsterile container.
2. Samples not transported and received at 0-4.4°C.
3. Sample exceeding time limit.
4. No temperature control.

Interpretation: High levels of somatic cells are indicative of poor animal health or practices.
Method: Single Strip.
Normals/reference Interval: 750,000/ml. Limit.
Cautions or Limitations: Primarily dependent on individual analyst's expertise in reading slides.
Reference: Standard Methods For the Examination of Dairy Products.
Charge: N/A-Enforcement only.

Special Immunology

Ehrlichia Serology

Synonyms: Ehrlichiosis, Human Ehrlichiosis
Useful For: Aid in the diagnosis of Human Ehrlichiosis
Request Form: SRD-1

Specimen: Serum
Volume: 3 ml
Container: Red top tube
Collection: Acute and convalescent serum is recommended.
Storage Instructions: Refrigerate
Causes for Rejection: Gross bacterial contamination
Interpretation: A single specimen with a titer >1:128 is suggestive of Ehrlichiosis. A four-fold or greater rise in titer between acute and convalescent sera is confirmatory.
Method: Indirect fluorescent antibody (IFA)
Normals/Reference Interval: Negative
Cautions or Limitations: Tests using the canine strain, Ehrlichia canis, will not detect all cases of Human Ehrlichiosis.
NOTE:
1. Tick Identification available, see Lyme Disease, Tick Identification.
2. PCR testing available in near future.

Reference:
1. Fishbein DB and Dawson JE, "Ehrlichiae". In Manual of Clinical Microbiology, 5th ed. Balows A, Hausler WJ Jr, Herrmann KL, et al eds. Washington DC: American Society for Microbiology 1991, l054-58.
2. Maeda K, Markowits N, et al. Human Infection with Ehrlichia canis, a Lewkocyte Rickettsia. N Engl J Med 1987; 316:853-6.
3. Taylor JP, Batz TG, Fishbein DB, Roberts MA, Dawson J, and Ristic M. 1988. Serological Evidence of Possible Human Infection With Ehrlichia in Texas. J. Infect. Dis. 158:217-220.
4. Dawson J, Ewing SA, Human Ehrlichiosis, A Potentially Fatal Tick-Borne Disease, Journal of Spirochetal and Tick-Borne Diseases. Vol. 2, No.3:19-22, 1995.

Charge: Call for pricing.

Bacteriology

Enterococci - Water and Wastewater Analysis

Synonyms: Subgroup of Fecal Streptococci; E. Faecalis, E. faecium, E. gallinarum, and S. Avium

Useful For: Bacterial indicator for determining the extent of fecal contamination of surface water.
Request Form: Bact. 52; Chem. 44, or Chem. 40.
Specimen: Non-potable water, fresh and marine.
Volume: Minimum volume 100 ml.
Container: 125 or 250 ml sterile bottles or single service containers supplied by NJDOH.
Collection: Refer to Standard Methods For the Examination of Water and Wastewater for proper sampling procedure.
Storage Instructions: Maintain samples. Submit sample within 6 hours of collection. Submit samples to Room 237, ECLIS, State Health Department Laboratory Building.
Cause for Rejection:
1. Incorrect or outdated sample containers.
2. Samples exceeded mandated transport time limits.
3. Samples not transported and received cold. Preferably at 0-4.4°C.

Interpretation: The occurrence of enterococci indicates fecal contamination from warm blooded animals.
Method: Membrane filter/Multiple Tube Fermentation Method (MPN).
Normal/reference Interval: Refer to Bathing and Surface Water Regulations NJDEPE.
Cautions or Limitations: Measure fecal contamination of naturally occurring fresh waters with the fecal coliform test and marine waters with the enterococci test. It is advantageous to use bath fecal coliforms and Enterococci as indicators of fecal contamination.
Reference: Standard Methods For the Examination of Water and Wastewater. Microbiological Methods For Monitoring the Environment.
Charge: MPN - $16, MF - $22

Viral Serology

Ebstein-Barr Virus - FIA (Viral capsid antigen)

Synonyms: EBV, fluorometric immunoassay, mononucleosis

Useful For: Determining the EBV specific antibodies in serum or plasma. May be used to assess immune status with a single specimen.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 2-5ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of >1:14 is considered reactive.
Method: Fluorometric immunoassay
Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.
Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Diagnostic Virology

Encephalitis Virus Isolation

Synonyms: Eastern encephalitis, herpesvirus encephalitis

Useful For: Determining the etiology of a suspected viral infection.
Request Form: SRD-1
Specimen: Brain tissue
Volume: Biopsy or postmortem brain tissue.
Container: Sterile, dry, screw cap jar.
Collection: Postmortem tissue should be collected within 24hrs of death.
Storage Instructions: Specimens should be stored at 4°C and delivered to the laboratory within 24hrs of collection.
Causes for Rejection: Breakage, leakage of specimen containers or obvious bacterial contamination will be cause for rejection.
Interpretation: The presence of cytopathogenic effect (CPE) and/or symptomatic pathology in animal hosts systems are indicative of viral isolation.
Method: Inoculation in tissue culture and animal host systems.

Normals/Reference Interval: Failure to see CPE in tissue culture after two 7 day incubation periods and symptomatic pathology in animal hosts after a 21 day incubation period.
Cautions or Limitations: Failure to isolate a virus does not rule out the possibility of a viral infection.
Reference: Lennette, E.H. and N.J. Schmidt."Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections", 6th Edition, American Public Health Association, Washington, DC.
Charge: None

Diagnostic Virology

Enterovirus Isolation

Synonyms: Aseptic meningitis, myocarditis, pleurodynia, pericarditis, herpangina and hand, foot and mouth
Useful For: Determining the etiology of a suspected enterovirus infection.
Request Form: SRD-1
Specimen: Stools, rectal swabs, cerebral spinal fluid (CSF), throat swabs, brain biopsy tissue, etc.
Volume: Three consecutive stools (size of walnut), at least 0.5ml CSF, swabs in 2.0ml, 0.5% gelatin/saline solution or culturette.
Container: Swabs and CSF in screw cap tubes. Stools in sterile dry wide mouth screw cap jar.
Collection: Specimens should be collected within two weeks of onset of infection.
Storage Instructions: Specimens should be stored at 4°C and delivered to the laboratory within 24hrs of collection.
Causes for Rejection: Breakage, leakage of containers will be cause for rejection.
Interpretation: The presence of cytopathogenic effect (CPE) in tissue culture and/or symtomatic pathology in animal host systems are indicative of viral isolation.
Method: Inoculation in tissue culture and animal host systems.
Normals/Reference Interval: Failure to see CPE in tissue culture after two 7 day incubation periods and symptomatic pathology in animal hosts after a 21 day incubation period.
Cautions or Limitations: Failure to isolate a virus does not rule out the possibility of a viral infection.
Reference: Lennette, E.H. and N.J. Schmidt."Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections", 6th Edition, American Public Health Association, Washington, DC.
Charge: None

Bacteriology

Fecal Coliform - Water and Wastewater Analysis

Synonyms: Thermatolerant coliforms; E. Coli; Klebsiella, by MPN
Useful For: Indicators of fecal contamination in most types of water samples.
Note: Analyzed in conjunction w/total coliforms in all potable water samples.
Request Form: Bact. 52; Chem. 44; Pul2 or Chem. 40.
Specimen: Potable and all non-potable water to include sewage effluent, streams, salt or brackish waters, mud, sediments and sludge.
Volume: Minimum volume of 100 ml.
Containers: 125 or 250 ml sterile bottles or single service containers supplied by NJDOH.
Collection: Refer to Standard Methods For the Examination of Water and Wastewaters for proper sampling procedures.
Storage Instructions: Maintain samples at 0-4.4°C. Submit potable water samples within 30 hours and non-potable water within 6 hours of collection. Submit samples to Room 237, ECLIS, State Health Department Laboratory Building.
Causes for Rejection:
1. Incorrect or outdated sample containers.
2. Samples exceeded mandated transport time limits.
3. Samples not transported and received cold. Preferably at 0-4.4°C.

Interpretation: Fecal coliform bacteria are the primary indicators of contamination from Human, animal and stormwater runoff.
Method: Membrane Filer or Multiple Tube Fermentation Method (MPN) (See Total Coliform Membrane Filter).
Normals/reference Interval: Refer to Drinking Water Regulations under the Safe Drinking Water Act Criteria and Standards Division USEPA/Bathing and Surface Water Regulations NJDEPE.
Cautions or Limitations: Due to survival differences in various types of water samples, ie fresh versus marine, it is advantageous to analyze in conjunction with other indicator organisms when examining non-potable water.
Reference: Standard Methods For the Examination of Water and Wastewater. Microbiological Methods For Monitoring the Environment.
Charge: Membrane Filter - See Total Coliform. Multiple Tube Fermentation (MPN) - $17.

Bacteriology

Fecal Streptococcus - Water and Wastewater Analysis

Synonyms: Fecal Strep. MPN, Group D Strep; In the context of indicators
Useful For: Used as fecal pollution indicators in water. Should be used in conjunction with fecal coliform.
Request Form: Bact. 52, Chem. 44, or Chem. 40.
Specimen: Non-potable water sources.
Volume: Minimum volume 100 ml.
Container: 125 or 250 ml sterile bottles, or Single Service Containers supplied by NJDOH.
Collection: Refer to Standard Methods for the Examination of Water and Wastewater, for proper sampling procedures.
Storage Instructions: Maintain samples at 0-4.4°. Submit samples within 6 hours of collection. Submit samples to Room 237, ECLIS, State Health Department Laboratory Building.
Causes for Rejection:
1. Incorrect or outdated sample container.
2. Samples exceeding mandated transport time limits.
3. Samples not transported and received cold. Preferably 0-4.4°C.

Interpretation: Fecal streptococci serve as an index of fecal pollution of raw water and provide supplementary data when used in conjunction with thermo-tolerant coliforms.
Method: Multiple tube Fermentation Method (MPN).
Normals/references Interval: Refer to Bathing and Surface Water Regulations NJDEPE.

Cautions or Limitation: Fecal streptococci, as they relate to fecal contamination of water, are a valuable indicator when used as an adjunct to fecal coliforms. There are, however, members of streptococci that may be present and do not originate in the gut of warm blooded animals.
Reference: Standard Methods For the Examination of Water and Wastewater; Journal of Environmental Pathology, Toxicology and Oncology.
Charge: $14

ECLS-Biochemistry

Foods for Adulteration or Conformation to State Standards

Synonyms: Product Tampering, Food Chemistry
Useful For: Determination of adulteration of foods. Qualitative and quantitative determination of proper ingredients.
Request Form: CHEM-40,40A
Specimen: Any food product
Volume: Variable with assay
Container: Any suitable container
Collection: Variable, depending on food
Storage Instructions: Variable with sample
Causes for Rejection: Insufficient sample, spoilage, no approval from Food and Milk program.
Interpretation: These results are for public health reasons only. They are not to be used as evidence in litigation.
Method: Variable. All from AOAC or USP
Normals/Reference Interval: Variable
Cautions or Limitations: Must have approval from Food and Milk Program, Consumer Health Services before testing can be done.
Reference: *Official Methods of the Association of Analytical Chemists*, 1995, 16th Ed.; *US Pharmacopeia 23, National Formulary 14*, 1995.
Charge: None, sample analysis must be prior approved by the New Jersey Department of Health's Consumer Health Services program.

Special Immunology

Fungal Serology

Synonyms: Fungal Immunodiffusion, Fungal ID, Fungal Antibodies Qualitative
Useful For: Aid in the diagnosis of aspergillosis, histoplasmosis, blastomycosis, and coccidioidomycosis.
Request Form: Form: SRD-1
Specimen: Serum
Volume: 3 ml
Container: Red top tube
Collection: Acute and convalescent sera are recommended, especially when acute titers are only presumptive. Collect aseptically with patients in fasting state.
Storage Instructions: Refrigerate
Causes for Rejection: Inadequate labeling, excessive hemolysis, lipemic serum, gross contamination of the specimen.
Interpretation: Tests in which the control precipitin bands are present and "identity" bands are formed with the patient specimen should be reported as "positive".
Method: Immunodiffusion (ID)
Normals/Reference Interval: Negative. No precipitin bands.
Cautions or Limitations: IgM antibodies frequently predominate in patients with early, primary infection (first 3-6 weeks), and diffuse slowly in the gel due to their large molecular size. A negative test does not exclude a fungal infection.
Reference:
1. Kaufman L and Reiss E, "Serodiagnosis of Fungal Diseases", Manual of Clinical Laboratory Immunology, 4th ed. Vol, 2, chapter 78 Rose NR, Conway de Macario E, Fahey JL, et al, eds, Washington, DC: American Society for Microbiology, 1992, 506-28.
2. Kaufman L. 1973. Value of Immunodiffusion Tests in the Diagnosis of Systemic Mycotic Diseases. Ann. Clin. Labs. Sci. 3:141-146.
3. Package Insert Immuno-Mycologic, Inc. ID Kit.
Charge: None

Bacteriology

Gonococcus Culture

Synonyms: Culture for GC only; Culture for Neisseria gonorrhoeae only; GC Screen; Gonorrhea Culture
Useful For: Isolation and identification of N. gonorrhoeae. Approval from the STD Control Program (609-588-7526) is required prior to submission of specimens.
Request Form: Bact. 24
Specimen: Culture of body fluid, discharge, pus, swab of genital lesions, urethral discharge (best for men when available), throat swab, rectal swab.
Volume: One swab inoculated onto New Jersey Modified Thayer Martin Media.
Container: New Jersey Modified Thayer Martin (NJ-MTM) Media available from the laboratory. Prewarm plate before inoculation.
Collection: Urethral discharge: Collect male urethral discharge by endourethral swab after stripping toward the orifice to express exudate.
Endocervical canal: Moisten speculum with warm water; do not use any other lubricant. Remove excessive cervical mucus. Insert sterile cotton-tipped swab into endocervical canal, move swab from side to side; allow 10-30 seconds for absorption of organisms onto the swab.
Anal canal (also called rectal culture): Insert sterile cotton tipped swab approximately one inch into the anal canal. Move swab from side to side to sample crypts; allow 10-30 seconds for absorption of organisms onto the swab.
Urethra or vagina (Cultures are indicated when the endocervical culture is not possible such as in hysterectomy patients and children.)

Urethra: Strip the urethra toward the orifice to express exudate. Use sterile loop or cotton swab to obtain specimen.
Vagina: Use speculum to obtain from the posterior vaginal vault or obtain specimen from the vagina orifice if the hymen is intact.

Oropharynx (a common local source for disseminated gonococcal infection): Swab the posterior pharynx and tonsillar crypts with a cotton-tipped applicator.
Bartolin gland: Express exudate from duct. Abscesses should be aspirated with needle and syringe.
See Table 1 for proper inoculation of plates.
Storage Instructions: Do not refrigerate inoculated NJ-MTM media. After inoculation, place directly in CO2 incubator or candle jar and incubate at 35-36 C. After a minimum incubation period of 18-24 hours, remove culture plates from their respective jars and transfer them to carrier carton in stacks of 6 for state courier pick-up. All plates must remain inverted and each stack must be immobilized with masking tape. Do not tape

each plate individually unless only one plate is being submitted.
Causes for Rejection: Culture plates that are broken or destroyed in transit will not be processed.
Interpretation: If gram negative diplococci are seen which are oxidase positive, are from a cervical or urethral culture and exhibit typical morphology, then this combination provides sufficient criteria for the presumptive identification of Neisseria gonorrhoeae.
If any of these criteria are not met, the organism must be definitively identified with additional tests. Organisms from the throat or rectum and isolates from infants or children under the age of twelve years are confirmed by biochemical tests such as chromogenic enzyme substrate tests and acid from carbohydrates and serologic tests that employ monoclonal antibodies.
Method: Culture on the selective NJ-MTM media.
Normals/Reference Interval: Gonococcus not found.
Cautions or Limitations: Culture is screened for Neisseria gonorrhoeae. No other organisms are identified routinely.
Reference: Balows, A., W.J. Hausler, Jr., K.L. Herrmann, H.D. Isenberg, and H.J. Shadomy (ed.). 1991. Manual of Clinical Microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
Centers for Disease Control. 1983. Procedures for use by the laboratory in the isolation and identification of Neisseria gonorrhoeae. U.S. Dept. of Health and Human Resources, Atlanta, Georgia.
Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Yoken. 1995. Manual of Clinical Microbiology, 6th ed. American Society for Microbiology, Washington, D.C.
Charge: NJSDH IN-KIND Testing is provided to sites with > 2% positivity rates. The word "INKIND" is stamped in the upper right hand section of the agency address section of the Bact. 24 request form.
NJSDH PURCHASED Testing is done via the placement of a purchased "lab stamp" on the back of the Bact.24 request form. " Lab stamps' are $2 and are purchased from the NJSDH Laboratory.

TABLE 1

Inoculate the NJ-MTM plates by rolling the swab on the media first and then cross streak with the tip of the swab. Inoculate in the following pattern:
A. Roll swab
B. Cross streak using entire plate.

Diagnostic Virology
Hepatitis A IgM Antibody
Synonyms: Anti-HAV IgM, infectious hepatitis
Useful For: Determining the etiology of a suspected hepatitis virus infection.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 3-5ml
Container: Vacutainer tube (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: 2-8°C, long term storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient serum to perform assay.
Interpretation: Spectrophotometric readings exceeding a cutoff established with kit controls are considered reactive and indicate a current illness.
Method: Enzyme immunoassay
Normals/Reference Interval: The reactive cutoff is established by multiplying the mean of the negative controls by a constant.
Cautions or Limitations: The assay determines only anti-HAV IgM titers. Since it does not measure IgG titers it can not be used to determine immune status of the patient.
Reference: Engvall, E. and P. Perlmann, "Enzyme-linked immunosorbent assay quantitative assay of immunoglobulin G", Immunochem. 1971. 8:871-874.
Charge: $10

Diagnostic Virology
Hepatitis B Core Antibody
Synonyms: HBc Ab
Useful For: Determining the antibody to Hepatitis B Core antigen in serum or plasma.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 3-5ml
Container: Vacutainer tube (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: 2-8°C, long term storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient serum to perform assay.
Interpretation: Spectrophotometric readings exceeding a cutoff established with kit controls are considered non-reactive and indicate no history of infection with hepatitis B.
Method: Enzyme immunoassay
Normals/Reference Interval: The reactive cutoff is established by multiplying the mean of the positive controls by a constant.
Cautions or Limitations: No confirmatory assay is available for the presence of anti-HBc.
Reference: Engvall, E. and P. Perlmann, "Enzyme-linked immunosorbent assay quantitative assay of immunoglobulin G", Immunochem. 1971. 8:871-874.
Charge: $10

Diagnostic Virology
Hepatitis B Surface Antigen
Synonyms: HBs Ag, serum hepatitis, Australia antigen
Useful For: Determining the etiology of a suspected hepatitis virus infection.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 3-5ml
Container: Vacutainer tube (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: 2-8°C, long term storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient serum to perform assay.
Interpretation: Spectrophotometric readings exceeding a cutoff established with kit controls are considered reactive and indicate a current illness or chronic infection.
Method: Enzyme immunoassay
Normals/Reference Interval: The reactive cutoff is established by multiplying the mean of the negative controls by a constant.

Cautions or Limitations: Some specimens are repeatedly marginally reactive and must be confirmed using a neutralization confirmatory assay. Failure to identify HBs Ag does not rule out the possibility of a viral hepatitis.
Reference: Engvall, E. and P. Perlmann, "Enzyme-linked immunosorbent assay quantitative assay of immunoglobulin G", Immunochem. 1971. 8:871-874.
Charge: $10

Diagnostic Virology

Hepatitis B Surface Antigen Confirmatory Assay

Synonyms: HBs Ag confirmatory test
Useful For: Confirming the presence of HBs Ag in marginally reactive assays.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 3-5ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: 2-8^{o}C, long term storage requires cell separation and freezing at -20^{o}C.
Causes for Rejection: Breakage, leakage or insufficient serum to perform assay.
Interpretation: HBs Ag reactive specimens are incubated with antibody specific for HBs Ag. If HBs Ag is present the specific antibody will compete for binding sites in the assay kit. The HBs Ag is competitively inhibited and rendered non-reactive which results in a reduction in signal. A specimen is confirmed positive for HBs Ag if the signal of the inhibited specimen is reduced by 50%.
Method: Competitive inhibition enzyme immunoassay.
Normals/Reference Interval: The specimen is run in duplicate with normal serum and specific antibody. The signals from each assay are compared.
Cautions or Limitations: Non-specific inhibitors can render some specimens non-confirmable.
Reference: Engvall, E. and P. Perlmann, "Enzyme-linked immunosorbent assay quantitative assay of immunoglobulin G", Immunochem. 1971. 8:871-874.
Charge: $10

Diagnostic Virology

Herpesvirus Isolation

Synonyms: Fever blister, herpes genitalis
Useful For: Determining the etiology of a suspected herpesvirus infection.
Request Form: SRD-1
Specimen: Lesion swabs or lesion scrapings.
Volume: Swabs in 2.0ml, 0.5% gelatin saline solution or culturette. Scrapings with scalpel should contain 100 - 200 cells from base of lesion.
Container: Swabs in sterile screw cap tube. Scrapings air dried on microscope slide.
Collection: Specimens should be collected when lesions are vesicular.
Storage Instructions: Swabs should be stored at 4^{o}C and delivered to the laboratory within 24hrs of collection. Slides of scrapings can be held at room temperatures and mailed to the laboratory in a slide container.
Causes for Rejection: Breakage, leakage or obvious bacterial contamination of swabs or insufficient cells on scraping slice will be cause for rejection.
Interpretation: The presence of cytopathogenic effect (CPE) in tissue culture and/or symptomatic pathology in animal host systems are indicative of viral isolation. Fluorescence of lesion cells using conjugated serum specific for herpesvirus in indicative an infection with Herpes simplex 1 or 2.
Method: Inoculation of swab specimens in tissue culture and animal host systems. Direct fluorescent antibody staining of lesion cells.
Normals/Reference Interval: Failure to see CPE in tissue culture after two 7 day incubation periods and symptomatic pathology in animal hosts after a 21 day incubation period.
Cautions or Limitations: Failure to isolate a virus does not rule out the possibility of a viral infection. There are no negative controls for lesion scrapings, therefore, the possibility of nonspecific staining and false positive results exists.
Reference:
1. Lennette, E.H. and N.J. Schmidt."Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections", 6th Edition, American Public Health Association, Washington, DC.
2. "Immunofluorescence Methods in Virology", Course No.8231-C, Public Health Service, Atlanta, GA.

Charge: None

Viral Serology

Herpes Simplex - FIA

Synonyms: HSV, fluorometric immunoassay
Useful For: Determining the HSV specific antibodies in serum or plasma. May be used to assess immune status with a single specimen or as a diagnostic test using acute and convalescent sera.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 2-5ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture. Paired specimens must be assayed together. Acute serum is collected within 7 days of onset and a convalescent specimen is collected at least 10 days later.
Storage Instructions: Specimens should be stored at 4^{o}C for up to 7 days, longer storage requires cell separation and freezing at -20^{o}C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of > 1:8 is considered reactive. An increase in titer between acute and convalescent specimens by a factor of 2.0 is indicative of a current infection.
Method: Fluorometric immunoassay
Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.
Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Bacteriology

Heterotrophic Plate Count

Synonyms: HPC pour plate, spread plate or membrane filter

Useful For: Enumeration of total numbers of viable bacteria in potable water.

Request Form: Bact. 52, PW 2 or Chem. 40.

Specimen: Potable water.

Volume: Minimum volume 100 ml.

Container: 125 or 250 ml. Sterile bottles or single service containers supplied by NJDOH.

Collection: Refer to Standard Methods For the Examination of Water and Wastewater for proper sampling procedures.

Storage Instructions: Maintain samples at 0-4.4°C. Submit potable water samples within 30 hours. Submit samples to Room 237, ECLIS, State Health Department Laboratory Building.

Causes for Rejection:

1. Incorrect or outdated sample containers.
2. Samples exceeding the mandated transport time limits.
3. Samples not transported and received cold. Preferably at 0-4.4°C.

Interpretation: HPC provides supportive data on the significance of coliform results. Judging the efficiency of water treatment processes. Checking quality of finished water in a distribution system.

Method: Pour plate/membrane filter.

Normals/references Interval: Refer to drinking water regulations under the Safe Drinking Water Act Criteria and Standards Division USEPA/NJDEPE (Water Resources).

Cautions and Limitations: Always consider bacteriological results in the light of available information on sanitary conditions associated with the source water. Single results should be considered as incomplete data by themselves. Base evaluation of water quality on a series of samples over a specified time period in conjunction with a sanitary survey.

Reference: Standard Methods For the Examination of Water and Wastewater.

Charge: $6

Viral Immunology

HIV-1 Immunophenotyping

Synonyms: Absolute CD-4 count, HIV-1 flow cytometry

Useful For: The CD-4 count is used to define a patient as AIDS positive versus being HIV-1 seropositive.

Request Form: Immunophenotyping Test Result

Specimen: Whole blood

Volume: 10 - 15ml

Container: Heparin coated vacutainer tube (brown top).

Collection: Venipuncture. Serial collections should be scheduled for the same time of day.

Storage Instructions: Room temperature (18 - 22°C)

Causes for Rejection: Specimens will not be processed if they are greater than 48hrs old, are clotted, hemolyzed, broken or leaked.

Interpretation: Analysis will provide absolute counts for all lymphocyte subsets, including helper T-cell, cytotoxic T-cell, B-cell and natural killer (NK) cell.

Method: Whole blood is stained with fluorescently conjugated monoclonal antibodies specific for lymphocyte subset markers. Red cells are reduced to debris using ammonium chloride. The flow cytometer distinguishes white cells based on light scatter and fluorescent color. The lymphocyte population subsets are analyzed and a comprehensive report is provided.

Normals/Reference Interval: Semiannual or quarterly testing of HIV-1 antibody positive individuals provide care-givers with CD-4 levels. CD-4 counts of less than 500 require PCP prophylactic intervention, while counts less than 200 meet the AIDS definition.

Cautions or Limitations: Specimens must be received in a timely fashion to complete an accurate analysis. Lymphocyte populations are effected by a number of drugs and follow a diuranal cycle. These factors must be considered in evaluating absolute counts.

Reference: "Guidelines for the Performance of CD-4+ T-cell Determinations in Persons with Human Immunodeficiency Virus Infection". MMWR:41, 1992.

Charge: $50

Diagnostic Virology

Human Immunodeficiency Virus Type 1 EIA

Synonyms: HIV-1 enzyme immunoassay

Useful For: Determining the presence of circulating HIV-1 specific antibodies in serum or plasma and is indicated as an aid in the diagnosis of potential infection with HIV-1.

Request Form: SRD-1; Counseling and Test Site Request for Testing

Specimen: Serum or plasma

Volume: 2-5ml

Container: Vacutainer (red, brown or violet top)

Collection: Venipuncture

Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.

Causes for Rejection: Breakage, leakage or insufficient quantity for testing.

Interpretation: Spectrophotometric readings of specimens exceeding a cutoff established with kit controls are considered initially reactive. Specimens with absorbance values less than the cutoff value are considered not reactive and may be considered negative for antibodies to HIV-1. Initially reactive specimens which do not react in either of duplicate repeat tests are considered negative for antibodies. Repeatedly reactive specimens are tested by additional supplemental tests.

Method: Enzyme immunoassay

Normals/Reference Interval: The reactive cutoff is established by adding a constant of 0.150 to the mean of the negative controls.

Cautions or Limitations: A negative test result does not preclude the possibility of exposure to or infection with HIV-1.

Reference: HIV-1 EIA Assay Kit Package Insert

Charge:

Diagnostic Virology

Human Immunodeficiency Virus Type 1 Western Blot

Synonyms: HIV-1 confirmatory/supplemental testing

Useful For: Confirming the presence of circulating HIV-1 specific antibodies in serum or plasma and is indicated as an aid in the diagnosis of potential infection with HIV-1. It is intended for use as an additional, more specific test for HIV-1 antibodies in individuals whose serum or plasma has been found to be repeatedly reactive using screening procedures such as EIA.

Request Form: SRD-1; Counseling and Test Site Request for Testing
Specimen: Serum or plasma
Volume: 2-5ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: The viral bands of interpretive significance on a reactive HIV-1 Western blot are p24, gp41 and gp120/160. A positive result is indicated when any two of the three major bands of diagnostic significance are present. Any band reactivity which does not meet the criteria for a positive result as described above is considered indeterminate. Absence of band reactivity is reported as negative.
Method: Western Blot Strip
Normals/Reference Interval: Negative and low positive controls must be assayed with each run regardless of the number of samples to be tested. Band intensity on test strips must have an intensity greater than or equal to the gp41 on the low positive control.
Cautions or Limitations: A negative test result does not preclude the possibility of exposure to or infection with HIV-1. Individuals with HIV-1 infection may present incomplete patterns due to the natural history of AIDS or other immunodeficiency states. All samples interpreted as Indeterminate should be repeated using the original specimen. In addition, it is recommended that samples interpreted as Indeterminate be retested after six months, using a fresh specimen.
Reference: Interpretation and Use of the Western Blot Assay for Serodiagnosis of Human Immunodeficiency Virus Type 1 Infections. MMWR, 1989;38:S-7.
Charge:

Diagnostic Virology
Human Immunodeficiency Virus Type 2
Synonyms: HIV-2
Useful For: Determining the presence of circulating HIV-2 specific antibodies in serum or plasma and is indicated as an aid in the diagnosis of potential infection with HIV-2.
Request Form: SRD-1; Counseling and Test Site Request for Testing
Specimen: Serum or plasma
Volume: 2-5ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: Spectrophotometric readings of specimens exceeding a cutoff established with kit controls are considered initially reactive. Specimens with absorbance values less than the cutoff value are considered not reactive and may be considered negative for antibodies to HIV-1. Initially reactive specimens which do not react in either of duplicate repeat tests are considered negative for antibodies. Repeatedly reactive specimens are tested by additional supplemental tests.
Method: Enzyme immunoassay
Normals/Reference Interval: The reactive cutoff is established by adding a constant of 0.150 to the mean of the negative controls.
Cautions or Limitations: Most specimens that are positive for antibody to HIV-1 will also react in HIV-2 EIA due to cross-reactivity. Samples with repeatably reactive test results must investigated further with supplemental testing. A negative test result does not preclude the possibility of exposure to or infection with HIV-2.
Reference: HIV-2 EIA Assay Kit Package Insert
Charge:

ECLS-Biochemistry
Lead, Blood, Pediatric, Confirmation
Synonyms: BPb, lead, confirmation
Useful For: Monitoring exposure to lead
Request Form: CHEM-26
Specimen: Whole Blood
Volume: 1.0mL
Container: Tan top vacutainer, lead-free, sodium heparin (protect from light)
Collection/Preservation: Mix well after collection to minimize clotting
Storage Instructions: Refrigerate, protect from light
Causes for Rejection: Clotted specimen, insufficient sample volume
Interpretation: Whole blood lead levels <10*u*g/dL are considered normal in adults. Automatic call-back ≥20*u*g/dL.
Method: Graphite Furnace Atomic Absorption Spectrometry
Normal/Reference Interval: Blood lead levels of <10*u*g/dL are considered normal in children.
Cautions or Limitations: Blood lead analysis has the strongest correlation with toxicity.
Reference: Preventing Lead Poisoning in Young Children, US Public Health Service, Centers for Disease Control, Atlanta, Ga., Oct. 1991.
Charge: $9, $12 with EP

ECLS - Biochemistry
Lead, Blood, Pediatric, Screening
Synonyms: BPb, lead, screening
Useful For: Monitoring exposure to lead
Request Form: CHEM-26
Specimen: Whole Blood
Volume: 500*u*L
Container: Sarstedt microvette, CB1000, amber with green top, ammonium heparin
Collection/Preservation: Shake tube vigorously to minimize clotting, take precautions against contamination.
Storage Instructions: Refrigerate
Causes for Rejection: Clotted specimen, insufficient sample volume
Interpretation: Whole blood lead levels <10*u*g/dL of considered normal in adults. Automatic call-back ≥20*u*g/dL.
Method: Graphite Furnace Atomic Absorption Spectrometry
Normal/Reference Interval: Blood lead levels of <10*u*g/dL are considered normal in children.
Cautions or Limitations: Blood lead analysis has the strongest correlation with toxicity.
Reference: Preventing Lead Poisoning in Young Children, US Public Health Service, Centers for Disease Control, Atlanta, Ga.,Oct. 1991.
Charge: $9, $12 with EP

Special Immunology

Legionella Culture

Synonyms: Culture, Legionella species, Legionnaires' Disease Agent

Useful For: Isolate and identify Legionella Sp.

Request Form: SRD-1

Specimen: Lung tissue, other body tissue, pleural fluid, other body fluids, transtracheal aspirate, sputum (avoid saliva), bronchial washings, water, environmental samples.

Volume: 5 mls fluid, 2 grams lung, 1 liter water

Container: Sterile screw-capped container within metal container

Collection: Aseptic collection. Contamination from skin or other body surfaces should be avoided.

Storage Instructions: Refrigerate or freeze if more than 24-48 hour transport delay is anticipated.

Causes for Rejection: Specimen leaked in transit. Specimens contaminated on the outside of the container pose excessive risk to laboratory personnel.

Interpretation: Identification of Legionella species from culture provides a definitive diagnosis. Organisms isolated are identified to species level whenever possible.

Method: Culture on selective and nonselective media. Examine up to 14 days.

Normals/Reference Interval: Legionella species not isolated from culture.

Cautions or Limitations: Sputum (expectorated), bronchial aspirates, and other specimens having normal flora are subject to bacterial overgrowth and are not desirable as transtracheal aspirates, pleural fluid and biopsy material for culture. Sensitivity of cultures is relatively low (50%) to 80%); however, specificity is l00%. A direct fluorescent antibody smear without culture can be done to detect Legionella.

Reference:

1. Bopp CA, Sumner JW, et al. Isolation of Legionella spp. from Environmental Water Samples by Low-pH Treatment and Use of a Selective Medium.
2. Rodgers FG, Pasculle AW: Legionella. In Manual of Clinical Microbiology. Fifth Edition. Edited by A. Balows, WJ Hausler, Jr., KL Herrmann, et al. Washington, DC. American Society for Microbiology, 1991, pp 442-453.
3. Winn WC Jr, "Legionnaires' Disease: Historical Perspective", Clinic Microbiology Rev, 1988, 60-81.

Charge: Call for pricing.

Special Immunology

Legionella Direct FA

Synonyms: FA Smear for Legionella

Useful For: Determine the presence of Legionella organisms in direct FA smear of specimen, providing rapid diagnosis.

Request Form: SRD-1

Specimen: Lung biopsy, lung exudate, pleural fluid, other body fluid, transtracheal aspirate, sputum, bronchial washings.

Volume: 5 ml fluids, 2 grams lung biopsy, 5 ml sputum

Container: Sterile screw-capped container within metal container.

Collection: Aseptic collection. Contamination from skin or other body surfaces should be avoided.

Storage Instructions: Refrigerate

Causes for Rejection: Swab specimen. Specimen leaked in transit.

Interpretation: Greater than or equal to 25 bacteria per smear is reported positive except in sputum where 5 or more is positive.

Method: Direct Fluorescent Antibody (DFA)

Normals/Reference Interval: DFA negative for Legionella species

Cautions or Limitations: Staining for several serogroups may be necessary. False-positive reaction has been reported in a case of pleuropulmonary Tularemia and in cases of Campylobacter infection.

Reference:

1. Anderson LP and Bangsborg J, "Cross Reactions Between Legionella and Campylobacter Species", Lancet, 1992, 340:245.
2. Friedman H, Wider R, and Klein T, "Immunodiagnosic Assays for Legionellosis", Lab Management, 1983, 21:19-23.
3. Roy TM, Fleming D and Anderson WH, "Tularemic Pneumonia Mimicking Legionnaires' Disease with False-Positive Direct Fluorescent Antibody Stains for Legionella", South Med J. 1989, 82 (11):1429-31.

Charge: None

Special Immunology

Legionella Indirect Fluorescent Antibody

Synonyms: Legionella Titer, Legionnaires' Disease Antibodies

Useful For: Support for the clinical diagnosis of Legionnaires' disease; determine stage of disease

Request Form: SRD-1

Specimen: Serum

Volume: 2 ml

Container: Red top tube or serum separator tube

Collection: A convalescent sample is recommended to be drawn 3-6 weeks after acute sample

Storage Instructions: Refrigerate

Causes for Rejection: Hemolysis, Lipemia; gross bacterial contamination

Interpretation: A fourfold rise in titer >1:128 from acute to convalescent phase provides evidence of recent infection. A single titer ≥256 is evidence of infection at an undetermined time.

Method: Indirect Fluorescent Antibody

Normals/Reference Interval: Negative. Less than a fourfold change in titer between acute and convalescent samples; <1:256 in a single sample.

Cautions or Limitations: Due to the relatively high prevalence of antibodies to Legionella pneumophila, acute and convalescent titers are preferred to a single sample. Titers against antigens other than L. pneumophila serogroup 1 cannot be interpreted with current data. Legionellosis patients' sera often have titer against multiple Legionella antigens (species or serogroup specific with common antigens).

Reference:

1. Rodgers FG, Pasculle AW: Legionella. In Manual of Clinical Microbiology - Fifth Edition, Edited by A. Balows, WJ Hausler Jr, KL Herrman, et al. Washington, DC: American Society for Microbiology, 1991, pp 442-453.
2. Wilkinson HW, et al: Indirect Immunofluorescence Test for Serodiagnosis of Legionnaires' Disease. Journal of Clinical Microbiology, Mar. 1979, p 379-383.

Charge: None

Special Immunology

Legionella Urinary Antigen

Synonyms:

Useful For: An adjunct to culture for the presumptive diagnosis of past or current Legionnaires' Disease
Request Form: SRD-1
Specimen: Urine
Volume: 5 ml (minimum 0.5 ml)
Container: Standard sterile urine containers
Collection: First void preferred, avoid diuretic urine
Storage Instructions: Refrigerate
Causes for Rejection: Improperly labeled specimens
Interpretation: Ratio ≥ 3.0 Presumptive positive for presence of L. pneumophila serogroup 1 antigen in urine, suggesting current or past infection.
Method: Enzyme Immunoassay (EIA)
Normals/Reference Interval: Ratio <3.0
Cautions or Limitations: A negative test result does not rule out the possibility of infection due to other serogroups or Legionella species since this test only detects L. pneumophila serogroup 1 antigen. Therefore, culture of respiratory specimens, along with the direct detection of Legionella in clinical specimens by DFA or serum antibody by IFA, provides the most sensitive and comprehensive means for the diagnosis of Legionnaires' disease.
Reference:

1. Berdal BP, Farshy CE and Feeley JC. 1979. Detection of Legionella pneumophila Antigen in Urine by Enzyme-linked Immunospecific Assay. J. Clin. Microbial. 9:575-578.
2. Tang PW and Toma - 1986. Broad-sprectrum Enzyme-linked Immunosorbent Assay for Detection of Legionella soluble antigens. J. Clin. Microbial. 24:556-558.
3. Kohler RB, Winn WC Jr, and Wheat LJ. 1984. Onset and Duration of Urinary Antigen Excretion in Legionnaires' Disease. J. Clin. Microbiol. 20:605-607.

Charge: None

Special Immunology

Leptospira Serodiagnosis

Synonyms: Leptospirosis Antibody Titers
Useful For: Support the diagnosis of Leptospirosis.
Request Form: SRD-1
Specimen: Serum
Volume: 3 ml
Container: Red top tube
Collection: Acute and convalescent specimen taken 10-14 days apart are recommended.
Storage Instructions: Refrigerate
Causes for Rejection: Hemolysis, Lipemia, gross bacterial contaminants
Interpretation: A positive reaction in a single specimen is of limited significance. A four-fold increase in titer in paired sera is diagnostic of infection.
Method: Macroscopic slide agglutination
Normals/Reference Interval: Negative
Cautions or Limitations: The antigens used in the test are the ones most commonly causing disease, but there are many other serovars which might not be detected.
Reference: Larsen SA, Pope V, and Quan TS, "Immunologic Methods for the Diagnosis of Spirochetal Diseases", Manual of Clinical Laboratory Immunology, 4th ed. Vol 2, Chapter 73, Rose NR, Conway de Macario E, Fahey, JL, et al, eds. Washington, DC: American Society for Microbiology, 1992, 467-81.
Charge: None

Special Immunology

Lyme Disease, Darkfield Microscopy

Synonyms:
Useful For: Detection of possible Lyme disease causing Spirochetes.
Request Form: SRD--1
Specimen: Tick, CSF, Synovial Fluid, EM Scrapings
Volume: 1-2 ml CSF, Synovial Fluid
Container: Airtight container, sterile CSF tube, sterile test tube
Collection: Aseptically collect CSF, Synovial Fluid. Remove embedded ticks with tweezers.
Storage Instructions: Refrigerate CSF, Synovial Fluid. Submit ticks in container with moistened paper towel, cotton or filter paper to maintain humidity and prevent desiccation.
Causes for Rejection: Ticks non-viable, submitted in alcohol, dessicated.
Interpretation: Spirochetes observed by Darkfield microscopy.
Method: Darkfield Microscopy
Normals/Reference Interval: No spirochetes observed.
Cautions or Limitations: The non-observance of spirochetes does not rule out the presence of spirochetes in the tick and, on the other hand, the observance of spirochetes does not automatically mean transmission has occurred.
Reference:

1. Kaslow RA, "Current Perspective on Lyme Borreliosis", JAMA, 1992, 267(10) = 1381-3
2. Steere A, Yrodzicki RL, Lornslatt V, Craft S, Barborer A, Burgdorfer W, et al, The Spirochetal Etiology Lyme Disease, N. Engl J. Med. 1983; 308:733-40
3. Updates: Lyme Disease - United States MMWR L984; 33:268-70

Charge: $20 (includes Lyme Disease-Tick Identification)

Special Immunology

Lyme Disease, Isolation and Cultivation

Synonyms: Spirochetes - Borrelia burgdorferi Spirochete isolation
Useful For: To confirm possible transmission of Lyme disease causing spirochetes.
Request Form: SRD-1
Specimen: Ticks, CSF, Synovial Fluid, EM Scrapings
Volume: 1-2 ml CSF, synovial fluid
Container: Air tight container, sterile CSF tube, sterile test tube
Collection: Aseptically collect CSF and synovial fluid, remove embedded tick with tweezers.
Storage Instructions: Refrigerate CSF, synovial fluid. Submit ticks in container with moistened paper towel, cotton, or filter paper to maintain humidity and prevent dessication.
Causes for Rejection: Ticks non-viable, submitted in alcohol, dessicated
Interpretation: Borrelia burgdorferi isolated in culture, confirmed by IFA.
Method: BSK-H and BSK-H-K-5 culture media. Hold for 28 days before reporting negative.
Normals/Reference Interval: Borrelia burgdorferi not isolated.

Cautions or Limitations: Live ticks only are cultured. The number of spirochetes observed may be too low to confirm as B. burgdorferi. The non-observance of spirochetes in culture does not rule out the presence of spirochetes in the tick, and on the other hand, the observance of spirochetes does not automatically mean transmission has occurred. Not all ticks carry spirochetes, and prolonged attachment is required for transmission.

Reference:

1. Barbour AG, Isolation and cultivation of Lyme disease Spirochetes. Yale Journal of Biology and Medicine 57:521-525, 1984.
2. Johnson SE, Klein GC, Schmid GP, Bowen GS, Feeley JC, Schulze T, Lyme Disease: A Selective Medium for Isolation of Suspected Etiological Agent, A Spirochete. J. Clin, Mic. 1984. 1981-82.
3. Pollack RJ, et al, Standardization of Medium for Culturing Lyme Disease Spirochetes. J. Clin. Mic. May 1993, p.1251-1255.

Charge: $20 (includes Lyme Disease-Tick Identification, Lyme Disease-Darkfield Microscopy)

Special Immunology

Lyme Disease Serology

Synonyms: Lyme Titer, Borrelia burgdorferi Antibodies

Useful For: Aid in the diagnosis of Lyme disease.

Request Form: SRD-1

Specimen: Serum or Cerebrospinal fluid

Volume: 2-3 ml

Container: Red top tube; sterile CSF tube

Collection: Specimens should be free from hemolyis, lipemia, gross bacterial contamination. A convalescent sample is recommended to be drawn 6-12 weeks from onset of symptoms.

Storage Instructions: Refrigerate

Causes for Rejection: Hemolysis, lipemia, gross bacterial contamination, multiple freeze/thaw cycles.

Interpretation: Data obtained from testing serum specimens suggest that IFA titers of ≥256 can be used as evidence of Lyme disease in patient with compatible clinical symptoms; a positive Western blot is confirmatory for Lyme disease.

Method: Indirect Fluorescent Antibody, ELISA, Western Blot (IgG and IgM)

Normals/Reference Interval: WB Negative. IFA titer <128; ELISA <1SD from the mean

Cautions or Limitations: IFA is relatively sensitive for patients with complicated Lyme disease and less sensitive for patients with ECM alone. Cross-reactions have been found in sera from patients with syphilis, but they can be distinguished with the RPR and MHA-TP tests. Sero negative Lyme disease has been reported. In early disease, a negative result does not exclude the diagnosis, and response may be blunted by antibiotics.

Reference:

1. Bakken LL, Case KL, Callistr SM, et al, "Performance of 45 Laboratories Participating in Proficiency Testing Program for Lyme Disease Serology", JAMA 1992, 268(7): 891-5.
2. Duffy J, Mertz, LE, Wobig GH, Katzman JA: Diagnosing Lyme disease: the contribution of serologic testing. Mayo Clin Proc 63:lll6-1121, 1988.
3. Dressler F, Whalen JA, Reinhardt BN, Steer AC: Western blotting in the serodiagnosis of Lyme disease. J Infect. Dis. 167:392-400 1993.
4. Russell H, et al; Enzyme-linked Immunosorbent Assay and Indirect Immunofluorescence Assay for Lyme disease. J. Infect. Dis. 1984; 149: 465-470.

Charge: $20

Special Immunology

Lyme Disease, Tick Identification

Synonyms: Deer Tick Identification, Black-legged Tick Identification

Useful For: Identify ticks carrying Borrela burgdorferi; causative agent of Lyme disease

Request Form: SRD-1

Specimen: Gross Arthropod

Volume:

Container: Airtight container, test tube

Collection: Remove embedded ticks with tweezers

Storage Instructions: Submit in container with moistened paper towel, cotton, or filter paper to maintain humidity and prevent desiccation.

Causes for Rejection:

Interpretation: Tick identified as Ixodes scapularies (black-legged tick formerly Ixodes dammini; deer tick), Amblyomma americanum (lone star tick), Dermacentor variabilis (dog tick).

Method: Macroscopic and microscopic evaluation

Normals/Reference Interval:

Cautions or Limitations: Not all ticks are potential Lyme disease carriers, and prolonged attachment is required for transmission. Routine testing of ticks is not recommended.

Reference:

1. Kaslow RA, "Current Perspective on Lyme Borreliosis", JAMA, 1992 267 (10):1381-3
2. Oliver JH, et al, "Conspecificity of the Ticks Ixodes scapularis and I.dammini (Acair's Ixodidae)". J. Med Entomol vol.30, No.1: 54-63. 1993.
3. Pratt HD and Smith JW, "Arthropods of Medical Importance", Manual of Clinical Microbiology, 5th Ed. Balows A, Hausler WJ Jr, Herrmann KL, et al, eds. Washington, DC: American Society for Microbiology 1991, 796-810.
4. Spielman A, Clifford CM, Piesman J, Corwin MD, "Human Babesiosis on Nantucket Island, USA: Description of the vector, Ixodes (Ixodes) Dammini, N.SP. (Acarina: Ixodidae)". J. Meds Entomol. vol. 15, no. 3: 218-234, l979.

Charge: $20 (includes Lyme Disease-Darkfield Microscopy, Lyme Disease-Isolation and Cultivation)

Viral Serology

Measles - FIA

Synonyms: Measles, fluorometric immunoassay

Useful For: Determining the measles specific antibodies in serum or plasma. May be used to assess immune status with a single specimen or as a diagnostic test using acute and convalescent sera.

Request Form: SRD-1

Specimen: Serum or plasma

Volume: 2-5ml

Container: Vacutainer (red, brown or violet top)

Collection: Venipuncture. Paired specimens must be assayed together. Acute serum is collected within 7 days of onset and a convalescent specimen is collected at least 10 days later.

Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.

Causes for Rejection: Breakage, leakage or insufficient quantity for testing.

Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of > 1:8 is considered reactive. An increase in titer between acute and convalescent specimens by a factor of 2.0 is indicative of a current infection.
Method: Fluorometric immunoassay
Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.
Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Viral Serology
Measles - M EIA
Synonyms: Measles IgM enzyme immunoassay
Useful For: Determining the presence of circulating measles specific IgM antibody in serum or plasma as an aid in the diagnosis of infection with or response to vaccination with measles virus.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 2-5ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture. Specimen should be collected no later than 2-4 weeks after onset.
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: Measles IgM antibody titers typically coincide with the onset rash in naturally infected individuals but may not appear for up to 2 weeks after administration of measles vaccine.
Method: Enzyme immunoassay
Normals/Reference Interval: The reactive cutoff is established by multiplying the mean of the negative controls by a constant.
Cautions or Limitations: A negative test for measles IgM antibodies does not exclude current measles infection. Serum that is not properly stored may give a false negative result. High levels of IgG and rheumatoid could cause false positive results.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Diagnostic Virology
Measles Virus Isolation
Synonyms: Rubeola, hard measles, red measles
Useful For: Determining the etiology of a suspected viral infection.
Request Form: SRD-1
Specimen: Throat swab, urine, nasopharyngeal swab.
Volume: Swab in 2.0ml, 0.5% gelatin saline solution or culturette. 5.0ml urine.
Container: Swabs in sterile screw cap tube. Urine in sterile screw cap jar.
Collection: Specimens should be collected within 7 days of onset of illness.
Storage Instructions: Specimens should be stored at 4°C and delivered to the laboratory within 24hrs of collection.
Causes for Rejection: Breakage, leakage of specimen containers or obvious bacterial contamination will be cause for rejection.
Interpretation: The presence of a multinucleated giant cell cytopathogenic effect (CPE) is indicative of viral isolation.
Method: Inoculation in tissue culture.
Normals/Reference Interval: Failure to see CPE in tissue culture after one two 7 day incubation periods.
Cautions or Limitations: Failure to isolate a virus does not rule out the possibility of a viral infection.
Reference: Lennette, E.H. and N.J. Schmidt."Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections", 6th Edition, American Public Health Association, Washington, DC.
Charge: None

Bacteriology
Microbiologic Analysis of Food Samples
Synonyms: Isolation, Enumeration and Identification of Potential Bacterial Pathogen in Food Samples, Trichinella Spiralis Food Assay
Useful For: The determination of the causative bacterial agent(s) during outbreaks of foodborne illness usually gastrointestinal in nature.
The Food Unit correlates with the Division of Epidemiology and Communicable Disease Control and or the Consumer Health Program during the analyses of foods submitted for bacterial studies. Fecal samples from ill patients as well as control samples are usually also analyzed concurrently with the food samples suspected of being the vehicles of transmission.
Request Form: Chem-40 Form obtained from the State Laboratory, or the local health authorities may substitute their forms utilized for general specimen collection. Alternatively, the appropriate State form may be completed at the time of delivery by local health department personnel.
Specimen: Any food item suspected or implicated of causing a food poisoning incident. Surveillance foods related to but not directly involved in illness may also be appropriate as the investigation warrants.
Volume: Optimally at least 200 grams of sample is appropriate if this much sample is available. This becomes critical if both qualitative; for example Salmonella, and enumerative; for example Clostridium perfringens are requested.
Legal samples for enumeration = 50 grams, and at least 25 grams are needed for qualitative analyses.
Container: Foods samples should be submitted in sterile, leak proof containers such as whirl-pak-bags or prior sterilized jars, bottles etc. The State does not supply such containers. They can be readily obtained from any biological supply house. Grocery store baggies, Styrofoam cups, or other non-terile containers present at a food establishment are not optimally acceptable and may not conform to the definition of a legal sample.
If whole samples are to be removed from a home residence, the containers they are in are acceptable providing they are leak proof.
Collection: All specimens should be taken under sterile conditions and the use of sterile spoons, knives and other utensils is necessary in food sampling.

In general, sample units taken from the geometric center of a food may yield the most likely isolation of a pathogen or where the highest counts may be found. Conversely, side layers of refrigerated product where cooling might occur most rapidly may represent the most accurate count that was present at the time of serving. Professional judgement at the collection site often dictates the collection technique.

For legal purposes, samples of foods from unopened packages of the same lot as the incriminated opened and eaten portion of food may be needed if commercial products are involved.

With prepared foods, various ingredients comprising the completed consumed product may also be collected. This could be important in some cases as it is often difficult or impossible to isolate ingredients of a prepared food for separate analyses.

All samples should be properly labelled, and the completed paperwork should identify source, lot numbers if applicable, where obtained at the source, where purchased, temperature at the time of collection, and any other pertinent information available.

Storage Instructions: Food samples should be kept under refrigeration from the time of collection until delivery to the State laboratory. Freezing of refrigerated product should be avoided as it causes cellular disruption and reduced bacterial counts during the thawing process. Freeze packs or ice (not dry ice) should be used for transport. However, if the foods are frozen when collected, they should be kept frozen until and during delivery.

Samples should be delivered to the laboratory as soon as possible as bacterial counts especially the Clostridia are reduced as time intervals before analysis increase. Foods stored under home freezer conditions are especially vulnerable due to the constant freeze-thaw cycle of the defroster mechanism.

Note: Optimal delivery is by personnel provided by the local health authority involved, directly to the State Laboratory. If the State courier system is utilized specimen delivery may be delayed or in some cases not result in the same day delivery of samples. If the State courier is utilized assure that the route is to be covered that day and not just leave the specimens at a pick up point.

Causes for Rejection:

1) Inadequate amounts, for example - less than 5 grams of sample. If tested, results may be qualified.
2) Gross temperature irregularities.
3) Lack of prior notification - All foods submitted must first be authorized by one or the other of two state agencies.
   A. Division of Epidemiology and Communicable Disease Control (609-588-7500).
   B. Consumer Health Unit (609-588-3123).

Prior notification is not only mandatory for authorization of analysis, but is also necessary in some cases, so that the laboratory can have specific media prepared that is usually only utilized on an as needed basis.

Interpretation: Foods are analyzed for organisms as authorized by Epidemiology with co-ordination of the submitting health authority and the laboratory. These can include:

1) Qualitative analyses - Salmonella sp., Shigella sp., Yersinia enterocolitica, Vibrio cholera and parahaemolyticus, E. coli 0157:H7, and as indicated less commonly occurring organisms such as Aeromonas hydrophila, Listeria monocytogenes, etc.
2) Enumerative analysis - Clostridium perfringens, Bacillus cereus, Staphylococcus aureus.
3) Toxin assays - Clostridium botulinum, Clostridium perfringens enterotoxin Type A, Staphylococcal enterotoxins Types A, B, C, D, and Bacillus cereus diarrheal toxin.
4) Parasitological analysis - Examination for the Nematode Trichinella spiralis.

Method: A variety of specific isolation media and enrichment techniques are utilized to select and enhance the isolation of specific bacterial pathogens. Some of these isolation media include: Mac Conkey, Mac Conkey with Ampicillin, Hektoen, Salmonella/Shigella, Brilliant Green, Mac Conkey with Sorbitol, TCBS, and CIN.

Enumeration techniques utilize plate dilution methods and in some cases most probable number analyses.

Toxin assays for C. perfringes, B. cereus, and S. aureus involve reverse passive latex agglutination.

C. botulinum toxin assays use the mouse neutralization test.

Food can be screened for E. coli 0157:H7 using an ELISA method in addition to culture analysis.

Testing for T. spiralis involves both a direct slide impression technique and an artificial digestion procedure which frees living larvae from meat samples, and a centrifugation step to concentrate them.

Normals/Reference Interval:

1) Qualitative techniques - The specific organism requested: not found.
2) Enumeration techniques - Optimally for Clostridium perfringens, Bacillus cereus, and Staphylococcus aureus the presence of greater or equal to 100,000/gram with the same organism isolated concurrently from patient fecal specimens.
3) Toxin assays - The specific toxin requested: not found.
4) Trichinella spiralis - Larvae not found.

Cautions or Limitations:

2) Enumerative analyses - Clostridium perfringens - sensitivity of analysis = 10/gram.
   Staphylococcus aureus and Bacillus cereus - sensitivity of analysis = 100/gram.

Any count for the above three organisms is reported, the significance is determined by clinical and epidemiologic information in addition to the laboratory results.

3) Reverse passive latex agglutination analysis:
   C. perfringens - 2 ng/ml. - False negatives may occur due to the difficulty in sporulation of this organism in artificial media.
   S. aureus - 1 ng/gram
   B. cereus - 4 ng/gram
4) T. spiralis - Larvae are slowly killed by freezing; analyses of frozen meat can result in false negative results. Sausage prepared by drying also results in inactivated larvae unable to be demonstrated by the digestive technique.

Detection limit of E. coli 0157:H7 by ELISA = < 0.003 to 2.4 per gram.

Reference:

1) AOAC International: Bacteriological Analytical Manual, 7th Edition, Arlington, VA, Food and Drug Administration, 1992.
2) Unipath Limited: The Oxoid Manual, 6th Edition, Basingstoke, Hampshire, England, 1990.
3) Murray R. (ed): Manual of Clinical Microbiology, 6th Edition, Washington, DC, American Society for Microbiology, 1995.

   Company, Minneapolis, Minnesota, 1986.
5) Bio Control Systems, Inc., 19805 North Creek Parkway,

Bothell; WA 98011.
Charge: There is no change involved for analyses of food samples authorized by the State Health Department.

Viral Serology
Mumps Virus - FIA
Synonyms: idemic parotitis, fluorometric immunoassay
Useful For: Determining the Mumps specific antibodies in serum or plasma. May be used to assess immune status with a single specimen.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 2-5ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of > 1:10 is considered reactive.
Method: Fluorometric immunoassay
Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.
Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Diagnostic Virology
Mumps Virus Isolation
Synonyms: Infectious parotitis
Useful For: Determining the etiology of a suspected viral infection.
Request Form: SRD-1
Specimen: Throat swab, nasopharyngeal swab, urine, cerebral spinal fluid (CSF).
Volume: Swabs in 2.0ml, 0.5% gelatin saline solution or culturette. 0.5ml CSF. 5.0ml urine.
Container: Swabs and CSF in sterile screw cap tube. Urine specimen in a sterile screw cap jar.
Collection: Specimens should be collected within 7 days of onset of illness.
Storage Instructions: Specimens should be stored at 4°C and delivered to the laboratory within 24 hrs. of collection.
Causes for Rejection: Breakage, leakage of specimen containers or obvious bacterial contamination will be cause for rejection.
Interpretation: The presence cytopathogenic effect (CPE) and hemadsorption (HAd) in tissue culture or hemagglutination (HA) in embryonated eggs are indicative of viral infection.
Method: Inoculation in tissue culture and embryonated eggs.
Normals/Reference Interval: Failure to see CPE and HAd in tissue culture after two 7 day incubation periods and HA in embryonated egg fluids after two 6 day incubation periods.
Coventional Biochemicals - As outlined in "Public Health Mycobacteriology. A Guide For The Level III Laboratory" (Ref
Cautions or Limitations: Failure to isolate a virus does not rule out the possibility of a viral infection.
Reference: Lennette, E.H. and N.J. Schmidt."Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections", 6th Edition, American Public Health Association, Washington, DC.
Charge: None

Mycobacteriology (Identification)
Mycobacterium Culture For Identification
Synonyms: AFB Culture and identification - Clinical and Referred
Useful For: Identification of Mycobacteria to the species level.
Request Form: Bact. 68, Bact. 109
Specimen: Isolated acid-fast bacillus submitted on L-J., 7H11 or Bactec 12B vial.
Volume: Any quantity of acid-fast growth.
Container: Media slant or vial shipped with completed paperwork in double-wall container.
Collection: Requires aseptic techniques and varies with specimen type & media.
Storage Instructions:
Clinical specimens: refrigerate
Referred specimens: incubate at 37 C
Causes for Rejection: Broken tube; grossly contaminated specimen
Interpretation: DNA Probes - DNA probe identifies Mycobacterium tuberculosis complex, Mycobacterium avium - intercellular complex, Mycobacterium gordonae, and Mycobacterium kansasii. Results of test are based on cut-off values.
HPLC - Identifies Mycobacterium to species level. Results of test are based on a Mycobacterium data base (Mycobacterium Library) compiled by James O. Kilburn et. al. CDC, Atlanta, GA. It is used in conjunction with a commercially available pattern recognition software package.
Conventional Biochemicals - As outlined in "Public Health Mycobacteriology. A Guide For The Level III Laboratory" (Ref #2).
Method: DNA Probes - Rapid identification of Mycobacteria based on specific ribosomal RNA sequences that are unique to specific Mycobacteria for which probes are available.
HPLC - Employs methodology for sample preparation and analysis which has been formulated at CDC, Atlanta, GA., by James O. Kilburn & W. Ray Butler.
Coventional Biochemicals - As outlined in "Public Health Mycobacteriology. A Guide For The Level III Laboratory" (Ref. #2).
Normals/Reference Interval: N/A
Cautions or Limitations: DNA Probes - M. tuberculosis complex does not differentiate between members of the TB Complex, ie; M. tuberculosis, M. bovis BCG, M. africanum, and M. microti.
The accuprobe M. avium complex culture identification identifies M. avium complex that belong to the complex based on biochemical methods, HPLC or GLC procedures. Rare isolates may not be positive.
HPLC - Requires experienced mycobacteriologist trained in proper sample preparation, equipment operation & analysis of data generated from procedure.

#2)
Reference:
1. Gen-Probe Incorporated
   9880 Campus Point Drive
   San Diego, CA 92121 1-800-523-5001
2. Public Health Mycobacteriology
   A Guide For The Level III Laboratory
   Patricia T. Kent, B.S.
   George P. Kubica, Ph.D.
   Division of Laboratory Training and Consultation
   Laboratory Program Office
   1985
   U.S. Department of Health and Human Services
   Public Health Service
   Centers for Disease Control
   Atlanta, Georgia 30333
3. Pierce, M. S.O.P. Mycobacteriology Lab. Manual - NJ State Dept. of Health 1995
4. Dillon, M. S.O.P. Mycobacteriology Lab Manual - NJ State Dept. of Health 1995
5. Cage, Gary D. "Direct Identification of Mycobacterium species in Bactec 7H12B medium By HPLC," J. Clinical Micro, Feb. 1994, Pg. 521-524
6. W. Ray Butler, Donald G. Ahearn, James O. Kilburn, "High Performance Liquid Chromatography Of mycolic Acids As A Tool In The Identification Of Corynebacterium, Nocardia, Rhodococcus And Mycobacterium Species," J. Clinical Micro, Jan. 1986, Pg. 182-185
7. Suzanne E. Glickman, James O. Kilburn, W. Ray Butler, L. Scott Ramos, "Rapid Identification of Mycolic Acid Patterns of Mycobacteria By High Performance Liquid Chromatography Using Pattern Recognition Software and a Mycobacterium Library" J. Clinical Micro, Mar. 1994, Pg. 740-745
8. ASTPHLD C.D.C Mycobacterium tuberculosis: Assessing your Laboratory March 1995.
Charge: $30

Viral Serology
Mycoplasma pneumoniae - FIA
Synonyms: Primary Atypical Pneumonia, fluorometric immunoassay, Eaton agent pneumonia, PPLO pneumonia
Useful For: Determining the Mycoplasma pneumoniae specific antibodies in serum or plasma. May be used to assess immune status with a single specimen or as a diagnostic test using acute and convalescent sera.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 2-5ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture. Paired specimens must be assayed together. Acute serum is collected within 7 days of onset and a convalescent specimen is collected at least 10 days later.
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of >1:16 is considered reactive. An increase in titer between acute and convalescent specimens by a factor of 2.0 is indicative of a current infection.
Method: Fluorometric immunoassay
Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.
Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Inborn Errors of Metabolism Program
Neonatal Galactosemia Metabolite Determinations
Synonyms: Galactose; galactose-1-phosphate
Useful For: Confirmatory neonatal screening for galactosemia; galactose and galactose-1-phosphate level determinations.
Request Form: IEM-1 and IEM-1a forms
Specimen: Blood
Volume: 100 ul/spot
Container: S&S #903 filter paper
Collection: Peripheral blood spotted onto S&S #903 filter paper (IEM-1 and IEM-1a form) and dried.
Storage Instructions: Cool, low humidity
Causes for Rejection: Specimen diluted, specimen over saturated or caked, specimen quantity insufficient, specimen not on S&S #903 filter paper, scratched or torn filter paper, filter paper detached from the form, specimen received >14 days from collection date.
Interpretation: Duplicate sample fluorescence is compared to positive controls of 4.5 and 9 mg/dL galactose. Fluorescence equal to or above the 9 mg/dL control is reported as a presumptive positive.
Method: Modified Hill for galactose levels
Normals/Reference Interval: <9 mg/dL galactose is NOT CLINICALLY SIGNIFICANT.
Cautions or Limitations: Results from children who have not had adequate milk feeding may be invalid.
Reference: Hill GN, O'Rielly D, Robertson E. A simple screening test for galactosemia based on accumulation of galactose and galactose-1-phosphate. In: Naruse H, Irie M, eds. Neonatal screening, Amsterdam: Elsevier Science Publishers, p. 252-253 (1983).
Charge: $27 (includes PKU, T4, Galactosemia and Hemoglobinopathy screening)

Inborn Errors of Metabolism Program
Neonatal Galactosemia Screening
Synonyms: Galactose-1-phosphate uridyltransferase deficiency; GALT
Useful For: Galactose-1-phosphate uridyltransferase deficiency identification
Request Form: IEM-1 and IEM-1a forms
Specimen: Blood
Volume: 100 ul/spot
Container: S&S #903 filter paper

paper (IEM-1 and IEM-1a forms) and dried.

Storage Instructions: Cool, low humidity
Causes for Rejection: Specimen diluted; specimen over saturated or caked; specimen quantity insufficient; specimen not on S&S #903 filter paper; scratched or torn filter paper; filter paper detached from the form; specimen received >14 days from collection date.
Interpretation: Sample fluorescence is compared to both positive and negative controls. Any sample showing a decreased fluorescence is repeated 4X and assayed by the secondary screening method for galactose. Presumptive positive samples are reported as showing no or partial fluorescence.
Method: Beutler
Normals/Reference Interval: Normal range is between 20 - 100% fluorescence; <20% fluorescent samples have partial enzyme activity and may be carriers or variant; 0% fluorescent specimens with no enzyme activity are presumptive positives.
Cautions or Limitations: Results from children who had blood transfusion are not valid; the fluorescent assay is sensitive to humidity and heat; galactokinase and epimerase deficiencies are not detected.
Reference: Beutler E and Baluda MC. Improved method for measuring galactose-1-phosphate uridyltransferase activity of erythrocytes. Clin. Chem. Acta 13:369-379 (1966).
Charge: $27 (includes PKU, T4, Galactosemia and Hemoglobinopathy screening)

Inborn Errors of Metabolism Program
Neonatal Hemoglobinopathy - Quantitative
Synonyms: Hemoglobin band quantity by area
Useful For: Determining the presence, types and relative concentrations of normal and variant hemoglobins, indicating possible disease and traits
Request Form: IEM-1 and IEM-1a forms
Specimen: Blood
Volume: 100 ul/spot
Container: S&S #903 filter paper
Collection: Peripheral blood spotted onto S&S #903 filter paper (IEM-1 and IEM-1a form) and dried
Storage Instructions: Cool, low humidity
Causes for Rejection: Specimen diluted, specimen oversaturated or caked, specimen quantity insufficient, specimen not on S&S #903 paper, scratched or torn filter paper, filter paper detached from the form, specimen received >14 days from collection date.
Interpretation: HPLC system analyzes by area, hemoglobins F, A, S, C, D, E/A2, and Bart's; IEF and HPLC results are correlated; inconsistent results by either IEF or HPLC are repeated by both isoelectric focusing and HPLC. Hemoglobins A, F, S, C, D, E, G, fast-movers, Bart's, and variant bands are reported.
Method: Secondary screening is HPLC analysis.
Normals/Reference Interval: Normal newborns present adult and fetal hemoglobin bands; other bands indicate disease or trait(s).
Cautions or Limitations: Some variant hemoglobin bands cannot be identified; results from children who had blood transfusions are not valid.
Reference:
1. Huisman, T.H.J.. Separation of hemoglobins and hemoglobin chains by High Performance Liquid Chromatography. J. Chromatogr.. 418:277 (1987).
2. Rogers BB. High Performance Liquid Chromatography in the Diagnosis of Hemoglobinopathies and Thalassemias, AM J Clin Pathol 84:671 (1985).

Charge: $27 (includes PKU, T4, Galactosemia and Hemoglobinopathy

Inborn Errors of Metabolism Program
Neonatal Hemoglobinopathy Screen
Synonyms: Hemoglobin bands
Useful For: Determining the presence and types of normal and variant hemoglobins, indicating possible disease states and/or carrier traits.
Request Form: IEM-1 and IEM-1a forms
Specimen: Blood
Volume: 100 ul/spot
Container: S&S #903 filter paper
Collection: Peripheral blood spotted onto S&S #903 filter paper (IEM-1 and IEM-1a form) and dried.
Storage Instructions: Cool, low humidity
Causes for Rejection: Specimen diluted, specimen oversaturated or caked, specimen quantity insufficient, specimen not on S&S #903 paper, scratched or torn filter paper, filter paper detached from the form, specimen received >14 days from collection date.
Interpretation: Any sample showing bands other than the expected A and F hemoglobins are repeated by isoelectric focusing and HPLC. Hemoglobins A, F, S, C, D, E, G, fast-movers, Bart's, and variant bands are reported.
Method: Primary screen is isoelectric focusing.
Normals/Reference Interval: Normal newborns present adult and fetal hemoglobin bands; other bands indicate disease or trait(s).
Cautions or Limitations: Some hemoglobins which migrate to the same position by gel electrophoresis (for example, hemoglobins E and A2) cannot be distinguished; some variant hemoglobin bands cannot be identified; results from children who had blood transfusions are not valid.
Reference:
1. Beuzard Y. et al, Isoelectric focusing of human hemoglobins, In: Hanash, Brewer eds. Advances in hemoglobin analysis. New York: Alan R. Liss, p.177-195 (1981).
2. Garrick MD, Dembure P, Guthrie R. Sickle-cell anemia and other hemoglobinopathies: procedures and strategy for screening spots of blood on filter paper as specimens. N Engl J Med 288:1265 (1973).

Charge: $27 (includes PKU, T4, Galactosemia and Hemoglobinopathy screening)

Inborn Errors of Metabolism Program
Neonatal PKU
Synonyms: Phenylketonuria, phenylalanine
Useful For: Identification and semi-quantitative determinations of phenylalanine levels.
Request Form: IEM-1 and IEM-1a
Specimen: Blood
Volume: 100 ul/spot
Container: S&S #903 filter paper
Collection: Peripheral blood on S&S #903 filter paper (IEM-1 or IEM-1a form) and dried.
Storage Instructions: Cool, low humidity

Causes for Rejection: Specimen not on S&S #903 filter paper; specimen not attached to form; quantity blood insufficient; specimen contaminated or diluted; specimen oversaturated; blood clotted or caked; filter paper torn or scratched; filter paper distorted; specimen received 14 days from collection date.
Interpretation: Convert the growth zone measurement of the specimen to the equivalent mg/dL phenylalanine from the measured standard; specimens with growth zones ≥4 mg/dL are retested after autoclaving; specimens with rings of inhibition are retested after autoclaving.
Method: Bacterial inhibition assay (Guthrie)
Normals/Reference Interval: <4 mg/dL is NOT CLINICALLY SIGNIFICANT; 4 mg/dL is borderline abnormal; 4-6 mg/dL is middle abnormal; 6 mg/dL and higher is presumptive positive.
Cautions or Limitations: Antibiotic interference
Reference:
1. Guthrie, R., Susi, A., A simple phenylalanine method for detecting phenylketonuria in large populations of newborn infants. Pediatrics 32:338, 1963.
2. Aldis, B.G., and Therrell, B.L., Automated BIA tray scanning in mass screening. In: Therrell, B.L., ed., Advances in neonatal screening. Amsterdam: Elsevier Science Publishers 507-10, 1987.
Charge: $27 (includes PKU, T4, Galactosemia and Hemoglobinopathy screening)

Inborn Errors of Metabolism Program
Neonatal T4 (total)
Synonyms: Thyroxine
Useful For: Low T4 levels as seen in primary, secondary or tertiary hypothyroidism or TBG deficiency.
Request Form: IEM-1 and IEM-1a
Specimen: Blood
Volume: 100 ul/spot
Container: S&S #903 filter paper
Collection: Peripheral blood on S&S #903 filter paper (IEM-1 or IEM-1a form) and dried.
Storage Instructions: Cool, low humidity
Causes for Rejection: Specimen not on S&S #903 filter paper; specimen not attached to form; quantity of blood insufficient; specimen contaminated or diluted; specimen oversaturated; blood clotted or caked; filter paper torn or scratched; filter paper distorted; specimens received >14 days from collection date.
Interpretation: T4 values ≥ 2.6 SD below the geometric mean value and repeat values ≥ 2.6 SD below the geometric mean value are reported as low T4; specimens exhibiting low values after repeat confirmation are assayed for TSH; specimens ≥ 1.3 SD from the geometric mean value or lowest 10% are assayed for TSH.
Method: Radioimmunoassay
Normals/Reference Interval: Normal T4 ranges using filter paper blood specimens from neonates, are reported as follows: specimens with a value above 1.3 SD from the geometric mean are reported as NOT CLINICALLY SIGNIFICANT; specimens ≥ 2.6 SD from the geometric mean value that repeat ≥ 2.6 SD from the geometric mean value are reported as LOW T4; specimens ≥ 1.3 SD from the geometric mean value are reported depending on the TSH value. Units-ug/dL.
Cautions or Limitations: TBG excess and hyperproteinemia may cause increased total thyroxine levels; TBG deficiency, hypoproteinemia, prematurity, improper collection, adverse transportation and storage of filter paper specimen; maternal drug ingestion; specimen punched directly from the center of the filter paper.
Reference:
1. Dussault, J.H., Coulombre, P., Laberge, C., Letarte, J., Guyda, H., and Khoury, K., Preliminary Report on a Mass Screening Program For Neonatal Hypothyroidism, J. Pediatrics, 86:670, 1975.
2. Larsen, P.R.,and Broskin, K., Thyroxine (T4) Immunoassay Using Filter Paper Blood Samples for Screening Neonates for Hypothyroidism, Pediatri, Res.,9:604, 1975.
Charge: $27 (includes PKU, T4, Galactosemia and Hemoglobinopathy screening)

Inborn Errors of Metabolism Program
Neonatal TSH
Synonyms: Thyroid stimulating hormone
Useful For: Diagnosis of primary hypothyroidism.
Request Form: IEM-1 and IEM-1a
Specimen: Blood
Volume: 100 ul/spot
Container: S&S #903 filter paper
Collection: Peripheral blood on S&S #903 filter paper (IEM-1 or IEM-1a form) and dried.
Storage Instructions: Cool, low humidity
Causes for Rejection: Specimen not on S&S #903 filter paper; specimen not attached to form; quantity of blood insufficient; specimen contaminated or diluted; specimen oversaturated; blood clotted or caked; filter paper torn or scratched; filter paper distorted; specimen received >14 days from collection date.
Interpretation: Test performed in duplicate; if the mean TSH values are <20 and one of the replicates is ≥20, the specimen is retested; if the mean TSH values are ≥20 and one of the duplicates is ≤20, the specimen is abnormal for TSH; if mean TSH values are ≥20 and there is a difference of more than 11 units between the replicates, the specimen is retested.
Method: Time-resolved fluoroimmunoassay
Normals/Reference Interval: <20 uU hTSH/mL normal; ≥20 uU hTSH/mL - 40 uU hTSH/mL borderline positive; >40 uU hTSH/mL presumptive positive.
Cautions or Limitations: Specimen spots punched too close to the edge of the blood spot; specimens collected at <24 hours of age may have elevated TSH values.
Reference:
1. Soini, E., and Kojola, H.: Time-resolved fluorometer for lanthanide chelates - a new generation of nonisotopic immunoassays, Clin. Chem. 29:65, 1983.
2. Lovgren, T., Hemmila, I., Pettersson, K., Eskola, J.U. and Bertoft, E.: Determinations of hormones by time-resolved fluoroimmunoassay, Talanta. 31:909, 1984.
Charge: $27 (includes PKU, T4, Galactosemia and Hemoglobinopathy screening)

Bacteriology
Ova and Parasite Examination
Synonyms: Parasitology Examination
Useful For: Diagnosis of Intestinal Parasites
Request Form: Bact. 3

Specimen: Stool
Volume: 25-50g
Container: Yellow labelled collection kit
Collection: Submit in a parasite preservative. Follow directions in the kit. Inoculate both formalin and PVA vials. Fresh feces should not be submitted. Other sources i.e. sputum, urine: Contact the laboratory (609-292-7369).
Storage Instructions: Maintain specimens at room temperature.
Causes for Rejection: Specimen unpreserved, specimen leaked in transit, specimen contaminated with interfering substances eg. castor oil, bismuth, barium, urine.
Interpretation: Amebic cysts, Crypto sporidium parvum oocysts, Giardia cysts and helminth eggs are recovered from formed stools. Mushy or liquid stools yield trophozoites and Crypto sporidium oocysts. PVA will preserve the trophozoite stage of protozoa. Formalin will preserve protozoan cysts and larvae and helminth ova.
Method: Formalin ethyl acetate concentration, Modified acid-fast staining, monoclonal indirect immunofluorescent stain, and trichrome stained slide.
Normals/Reference Interval: No parasites found.
Cautions or Limitations: One negative result does not rule out the possibility of parasitic infestation. Stool examination may be negative in early stages of Giardia infection.
Reference: Jacobs D., Demott W.,et al, Laboratory Test Handbook 3rd edition, Hudson, Ohio, Lexi-Comp Inc.,1994.
Charge: No charge for specimens referred by the Division of Epidemiology(609-588-7500) or submitted by Local Health Depts. All others $15.

Bacteriology

Parasite Examination, Blood

Synonyms: Blood Smear for Parasites, Plasmodium Smear
Useful For: Diagnosis of Blood Parasites
Request Form: Bact. 3
Specimen: Stained Blood Smears
Volume: Films(thick and thin)
Container: Slide mailer conforming to US Postal Regulations.
Collection: Air dry. Stain with Geimsa or Wright's Stain.
Storage Instructions: Maintain specimen at room temperature.
Causes for Rejection: Specimen broken in transit.
Interpretation: Release of trohpozoites and RBC debris results in a febrile response. Periodicity of fever correlates with the type of malaria. Organisms are most likely to be detected just before the onset of fever.
Method: Microscopic examination of thick and thin peripheral blood films.
Normals/Reference Interval: No parasites found.
Cautions or Limitations: One negative result does not rule out the possibility of parasitic infestation. If infection is strongly suspected, the test should be performed at least three times with samples obtained at different times in the fever cycle.
Reference: Jacobs D., Demott W., et al, Laboratory Test Handbook 3rd edition, Hudson, Ohio, Lexi-Comp Inc. 1994.
Charge: No charge for specimens referred by the Division of Epidemiology (609-588-7500) or Local Health Departments. All others $15.

Diagnostic Virology

Polymerase Chain Reaction for Human Immunodeficiency Virus 1

Synonyms: PCR/HIV-1 (clinical trial)
Useful For: Determining the presence of HIV-1 viral genome in human lymphocytes.
Request Form: PCR/HIV-1 Patient Case Report, Patient Consent
Specimen: Whole blood
Volume: 6-8ml ACD tube (Acid-Citrate-Dextrose, yellow top), 10-15ml dry tube (red top)
Container: Vacutainer tubes
Collection: Venipuncture
Storage Instructions: Specimens should be held at 2-8^{o}C.
Causes for Rejection: Breakage, leakage, clotting, hemolysis or specimens more than 3 days old will be cause for rejection.
Interpretation: Positive results indicate the presence of HIV-1 genomic material.
Method: Polymerase chain reaction.
Normals/Reference Interval: Viral genomic material is detectable before an immune response.
Cautions or Limitations: This procedure is currently undergoing clinical trials and testing is limited to; healthy homosexual, IV drug user, sexual contact of HIV infected individual, neonates of HIV infected mother and individuals with indeterminate HIV-1 serology.
Reference: Eisenstein, B., "The Polymerase Chain Reaction: A New Method of Using Molecular Genetics for Medical Diagnosis, N. Engl. J. Med., 1990; 332: 178-183.
Charge: None

Mycobacteriology

Primary Mycobacterial Antibiotic Susceptibility Testing

Synonyms: T.B. Sensitivity Testing
Useful For: To determine the susceptibility of the isolated organism to a panel of primary antimycobacterial drugs.
Request Form: Bact. 109 (Referred Cultures), Bact. 68 (Clinical Specimens).
Specimen: A pure culture of the organism to be tested.
Volume: Any quantity of acid fast organism.
Container: Slants: 7H11, L-J.
Liquid Media: 12-B, 13-A.
Collection: N/A
Storage Instructions: Maintain Specimen at 37^{o}C.
Causes for Rejection: Vial or slant broken in transit; non-separable contaminated culture; non-separable mixed mycobacterial culture; no identification on specimen.
Interpretation: Increase or decrease of growth index from Bactec 460 over a period of (5) to (10) days as compared to controls. Resistance is a measure of successive daily significant - often doubling - Growth Index (GI).
Level or decreasing Growth Index indicates sensitivity of the organism to the primary drugs:
1. Isoniazid (INH).
2. Streptomycin (SM).
3. Rifampin (RIF).
4. Ethambutol (EMB).

5. Pyrazinamide (PZA).

All at prescribed concentrations.

Method: Inoculation, incubation and daily run on Bactec-460 to determine the change (increase or decrease) in the Growth Index (GI).

Normals/Reference Interval: One set of control vials (12-B) per specimen. and, one set of Quality Control Organisms per inoculation date.

Cautions or Limitations: Requires sterile technique in a Level III Laboratory staffed by experienced Mycobacteriologists. Susceptibilities cannot be reported if the isolate fails to grow in the media.

Reference:

1. Siddiqi, S., Bactec 460TB System Product and Procedure Manual - 1995.
2. Pierce, M., S.O.P. Mycobacteriology Laboratory Manual - N.J. State Department of Health - 1995.
3. ASTPHLD, C.D.C. Mycobacterium Tuberculosis: Assessing Your Laboratory - March 1995

Charge: $30 for each specimen.

Bacteriology

Pulsed Field Gel Electrophoresis

Synonyms: PFGE, DNA typing, Epidemiological typing

Useful For: Identification of Outbreak related strains. Prior approval by the Division of Epidemiology (609-588-7500) is required before submission of specimens.

Request Form:

Specimen: Pure cultures grown on agar slants.

Volume: Viable colonies

Container: Agar slants with screw-cap closures in containers that conform to US Postal regulations.

Collection: Isolate organisms from various patient specimens. Grow in pure culture on appropriate media.

Storage Instructions: Maintain specimens at room temperature.

Causes for Rejection:

Interpretation: Comparative chromosomal banding patterns are categorized as: Identical; Closely related, differing by one genetic event (1 or 2 band difference; Possibly related, differing by two genetic events (2-3 band difference); and Different, differing by three or more genetic events (4 or more band difference). Letters will designate identical patterns i.e. A, B, C etc.. Related strains will be designated as A1, A2, A3, etc.

Method: Pulsed field gel electrophoresis of restriction enzyme digests of extracted DNA.

Normals/Reference Interval:

Cautions or Limitations: Organisms to be tested must be related to an outbreak of disease. For pathogens such as MRSA or H influenzae type b that represent genetically restricted subsets of strains within a species less variation is detected among unrelated isolates by genetic typing methods.

Reference: Bio-Rad Laboratories, The Gene Path(R) System Reference Manual Hercules, California, 1993.

Charge: No charge

ECLS-Biochemistry

Qualitative Urine Drugs of Abuse Screening

Synonyms: Drug Screen, EMIT Screen

Useful For: Screening of urine samples for the presence of drugs of abuse.

Request Form: LS-1

Specimen: Urine

Volume: 5.0mL

Container: Screw cap urine vial

Collection: Supervised voiding

Storage Instructions: Ambient temperature

Causes for Rejection: Volume less than 5.0mL; adulteration of sample

Interpretation: These homogeneous enzyme immunoassays are intended for use in the qualitative analysis of drugs of abuse in human urine.

Method: Enzyme Multiplicative Immunoassay (EMIT) for amphetamines, barbiturates, benzodiazepines, cocaine metabolite, methadone, opiates.

Normals/Reference Interval: Negative if below cutoff of assay. Positive if at or above cutoff level.

Cautions or Limitations: Results are merely indicative, not determinative, of the use of a drug. This test is not confirmatory.

Reference: EMIT II Drugs of Abuse Assays on the IL Monarch Chemistry Systems, 1991, Syva Co., Palo Alto, Ca.

Charge: $1.65 per drug assay

ECLS-Biochemistry

Quantitative Serum Phenylalanine and Tyrosine Analysis

Synonyms: Confirmatory PKU Analysis

Useful For: Confirmation of Phenylketonuria (PKU) in Newborns. Monitoring Phenylalanine and Tyrosine in PKU Patients.

Request Form: CHEM-27

Specimen: Serum, Whole Blood

Volume: 2.0mL

Container: Microtainer

Collection/Preservation: Heal or finger stick

Storage Instructions: Ambient temperature

Causes for Rejection: Volume less than 2.0mL; excessive hemolysis

Interpretation: Phenylalanine levels above 4.0mg% are suspect. Contact PKU specialist for further instructions.

Method: High Performance Liquid Chromatography (HPLC) with post-column fluorescence detection. The analytes are separated using HPLC then detected using a fluorescence detector.

Normal/Reference Interval:

4.0mg% (24.2umole/100mL) or below for Phenylalanine
3.5mg% (19.4umole/100mL) or below for Tyrosine

Cautions or Limitations: None

Reference: Mohan. A.G., Rosenkrans, A.M., and Shahied,S.I., HPLC Analysis for Phenylalanine and Tyrosine in Serum for PKU Diagnosis and Treatment, *American Laboratory*, Dec. 1989, p29-32.

Charge: None, sample analysis must be prior approved by the Department of Health's Special Child Health Services program.

Diagnostic Virology

Rabies Examination

Synonyms: Hydrophobia

Useful For: Determining the presence of rabies virus in brain tissue.

Request Form: VIR-16

Specimen: Brain tissue or head of suspected rabid animal.

Volume: N/A

Container: Leakproof container (heavy plastic wrap placed in a sealed container)
Collection: Remove head of animal within 5 days of bite or exposure.
Storage Instructions: Specimens should be stored at 4°C and transported to the laboratory on cold packs.
Causes for Rejection: Specimens where brain tissue is damaged, decomposed or destroyed will be cause for rejection.
Interpretation: Direct staining of viral inclusions with specific anti-rabies virus fluorescent conjugate is indicative of infection with rabies virus.
Method: Direct fluorescent antibody.
Normals/Reference Interval: Normal and rabies positive mouse brain suspensions are used to extract anti-rabies conjugate to eliminate non-specific reactivity.
Cautions or Limitations: The efficacy of the direct fluorescent antibody test is strongly affected by the condition of the specimen. Decomposition severely diminishes the sensitivity of the test. Negative results on decomposed tissues can not justify decisions against treatment of an exposed individual. A health professional should be consulted in these instances.
Reference: "The Natural History of Rabies; 2nd Edition", G.M. Baer, Editor, CDC Press, 1991.
Charge: None

Diagnostic Virology

Respiratory Syncytial Virus Isolation

Synonyms: RSV, acute respiratory disease, URI
Useful For: Determining the etiology of a suspected viral infection.
Request Form: SRD-1
Specimen: Throat swab, nasopharyngeal swab.
Volume: Swab in 2.0ml, 0.5% gelatin saline solution or culturette.
Container: Swabs in sterile screw cap tube.
Collection: Specimens should be collected within 24hrs of onset of illness.
Storage Instructions: Specimens should be stored at 4°C and delivered to the laboratory within 24hrs of collection. Freezing of specimens should be avoided.
Causes for Rejection: Breakage, leakage of specimen containers or obvious bacterial contamination will be cause for rejection.
Interpretation: The presence of a multinucleated syncytial cytopathogenic effect (CPE) is indicative of viral isolation.
Method: Inoculation in tissue culture.
Normals/Reference Interval: Failure to see CPE in tissue culture after one two 7 day incubation periods.
Cautions or Limitations: Failure to isolate a virus does not rule out the possibility of a viral infection.
Reference: Lennette, E.H. and N.J. Schmidt."Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections", 6th Edition, American Public Health Association, Washington, DC.
Charge: None

Diagnostic Virology

Respiratory Virus Isolation

Synonyms: Influenza, pneumonia, URI, pharyngitis, etc.
Useful For: Determining the etiology of a suspected respiratory virus infection.
Request Form: SRD-1
Specimen: Throat swabs, throat washes, nasal pharyngeal swabs, sputum, tracheal swab, lung tissue, etc.
Volume: Swabs in 2.0ml, 0.5% gelatin saline solution or culturette. Throat washes with 10ml, 0.5% gelatin saline solution.
Container: Swabs in sterile screw cap tube. Throat washes in sterile wide mouth screw cap jars. Tissue samples in sterile screw cap jar.
Collection: Specimens should be collected within 72hrs of onset of infection.
Storage Instructions: Specimens should be stored at 4°C and delivered to the laboratory within 24hrs of collection.
Causes for Rejection: Breakage, leakage of container or obvious bacterial contamination will be cause for rejection.
Interpretation: The presence of cytopathogenic effect (CPE) and hemadsorption (HAd) in tissue culture or hemagglutination (HA) in embryonated eggs are indicative of viral isolation.
Method: Inoculation in tissue culture and embryonated egg host systems.
Normals/Reference Interval: Failure to see CPE and HAd in tissue culture after two 7 day incubation periods and HA in embryonated egg fluids after two 72hr incubation periods.
Cautions or Limitations: Failure to isolate a virus does not rule out the possibility of a viral infection.
Reference: Lennette, E.H. and N.J. Schmidt."Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections", 6th Edition, American Public Health Association, Washington, DC.
Charge: None

Diagnostic Virology

Rocky Mountain Spotted Fever and Typhus - Indirect Fluorescent Antibody

Synonyms: RMSF-IFA, Murine typhus, Brill-Zinsser disease
Useful For: Serologic determination for the presence of antibody to Rickettsia rickettsiae and Rickettsia typhi.
Request Form: SRD-1
Specimen: Serum, acute and convalescent.
Volume: 2-5ml
Container: Vacutainer (red top)
Collection: Venipuncture. Acute serum should be collected as soon after onset as possible. Convalescent serum should be collected at 4 and 6 weeks.
Storage Instructions: Specimens should be stored at 4°C.
Causes for Rejection: Breakage or leakage of container will be cause for rejection.
Interpretation: A four fold rise in titer between the acute and convalescent sera is diagnostic of a current infection. Single serum specimens with titers of 1:128 or greater are considered presumptive evidence of infection at some undetermined time.
Method: Micro-dot Indirect fluorescent antibody.
Normals/Reference Interval: Negative and positive serum controls are included in the assay.
Cautions or Limitations: Antibiotic treatment initiated early in the course of infection may inhibit the immune response and require additional convalescent follow-up.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989
Charge: None

Diagnostic Virology

Rocky Mountain Spotted Fever - Direct Fluorescence

Synonyms: RMSF-FA

Useful For: Determining the presence of Rickettsia rickettsiae, in tick hemolymph.

Request Form: SRD-1

Specimen: Tick

Volume: N/A

Container: Small screw cap vial or jar with moistened cotten.

Collection: Remove tick from body promptly and carefully without crushing by gentle steady traction, to avoid leaving mouth parts in the skin.

Storage Instructions: Ticks must be maintained alive.

Causes for Rejection: Dessicated, dead or very small ticks will be cause for rejection.

Interpretation: Direct staining of rickettsial intercellular inclusions with specific anti-RMSF fluorescent conjugate is indicative of infection with Rickettsia rickettsiae.

Method: Direct fluorescent antibody.

Normals/Reference Interval: Normal and RMSF positive yolk sac controls are used are included in the assay.

Cautions or Limitations: Failure to stain RMSF inclusions does not rule out the possibility of an infection. A health professional should be consulted to determine if any treatment should be initiated.

Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.

Charge: None

Viral Serology

Rubella - FIA

Synonyms: German measles, fluorometric immunoassay

Useful For: Determining the rubella specific antibodies in serum or plasma. May be used to assess immune status with a single specimen or as a diagnostic test using acute and convalescent sera.

Request Form: SER-1 used for immune status determination; SRD-1 used for paired sera.

Specimen: Serum or plasma

Volume: 2-5ml

Container: Vacutainer (red, brown or violet top)

Collection: Venipuncture. Paired specimens must be assayed together. Acute serum is collected within 7 days of onset and a convalescent specimen is collected at least 10 days later.

Storage Instructions: Specimens should be stored at 4^{o}C for up to 7 days, longer storage requires cell separation and freezing at -20^{o}C.

Causes for Rejection: Breakage, leakage or insufficient quantity for testing.

Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of > 1:8 is considered reactive. An increase in titer between acute and convalescent specimens by a factor of 2.0 is indicative of a current infection.

Method: Fluorometric immunoassay

Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.

Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.

Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.

Charge: $10

Viral Serology

Rubella M - FIA

Synonyms: German measles, IgM fluorometric immunoassay

Useful For: Determining the rubella IgM specific antibodies in serum or plasma. May be used to assess immune status with a single specimen.

Request Form: SRD-1

Specimen: Serum or plasma

Volume: 2-5ml

Container: Vacutainer (red, brown or violet top)

Collection: Venipuncture

Storage Instructions: Specimens should be stored at 4^{o}C for up to 7 days, longer storage requires cell separation and freezing at -20^{o}C.

Causes for Rejection: Breakage, leakage or insufficient quantity for testing.

Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of >1:5 is considered indicative of a current infection.

Method: Fluorometric immunoassay

Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.

Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.

Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.

Charge: $10

Bacteriology

Salmonella serotyping

Synonyms: Salmonellosis, gastroenteritis

Useful For: Determination of specific serotypes of Salmonella and analysis of serotypes as part of the National Salmonella Surveillance System. Tracing of outbreaks both local and multi-state and availability of stored cultures for further testing such as PFGE or referral to the Centers for Disease Control.

Request Form: Bact. 109

Specimen: Pure cultures of Salmonella species on agar slants of appropriate media.

Volume: Viable Colonies

Container: Agar slant with screw-cap mailed in container that conform to US Postal regulations.

Collection: All Salmonella isolates must be submitted to the laboratory as stated in New Jersey Administrative Code 8:57-1.

Storage Instructions: Maintain specimen at room temperature.

Causes for Rejection: Culture broken or destroyed in transit will not be processed.

Interpretation: There are two species of Salmonella, S. enterica and S. bongori. The species Salmonella enterica is subdivided into six subspecies 1, 2, 3a, 3b, 4, 6. The majority of Salmonella serotypes belong to subspecies 1 and these serotypes are given names. Subspecies 1 strains are usually isolated from humans and warm-blooded animals. Subspecies 2 strains are common in reptiles and the environment and are rarely isolated from humans. Subspecies 3 were formally classified in the genus 'Arizona', they also are isolated from cold-blooded animals and the environment. Subspecies 4 is rarely isolated from humans. Subspecies 6 strains have been isolated from warm and cold-blooded animals and the environment: two were isolated from humans. Ten strains are in this subspecies. S bongori (formerly subspecies 5) strains are usually isolated from the environment. One strain has been isolated from a human.
Method: Organism is grown on solid media then agglutinated on a slide for somatic or 'O' antigens. Broth cultures are formalinized and tested in tubes at 50C with specific flagellar or 'H' antisera. The combination of somatic and flagellar types are identified using the Kauffman-White schema.
Normals/Reference Interval:
Cautions or Limitations: Organisms may be nonmotile. Complete serotyping is not possible in these cases since no flagellar antigen is present.
Reference: Identification and Serotyping of Salmonella and an Update of the Kauffman-White Scheme, McWhorter-Murlin and Hickman-Brenner, US Dept of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia.
Charge: No charge

Mycobacteriology

Secondary Mycobacterial Antibiotic Susceptibility Testing

Synonyms: AFB or TB Sensitivity Testing, Plate Sensitivities, Secondary Plate Sensitivities
Useful For: Determining which secondary drugs are effective against each multiple drug resistant Mtbc. isolate. Determining which drug concentrations are effective.
Request Form: Bact. 109, Bact. 68 (amended)
Specimen: Pure culture isolated from a primary clinical specimen submitted on an agar slant or a 12B or 13A Bactec vial.
Volume: N/A
Container: Media slant containing adequate growth or a Bactec vial, tightly sealed and properly identified with the patients name or other identifying mark. Shipped with completed paperwork in an approved double wall mailing container.
Collection: N/A
Storage Instructions: Maintain specimen at 37^0C.
Causes for Rejection: Slant or vial broken in transit. No growth on slant. No identification on specimen. Specimen overgrown with contaminant or mixed culture submitted which can not be purified.
Interpretation: Based upon the proportion method. If the proportion of viable colonies resistant to a particular drug is l% or greater than the total population tested that culture is resistant to that drug at the concentration tested. If the proportion of colonies is less than l%, the isolate is sensitive to that particular drug at the concentrated tested.
Method: A modified C.D.C. proportion 7H11 agar plate method is used. Incubation period requires twenty-one days. Drugs tested include: Ciprofloxacin, Amikacin, Ofloxacin, Cycloserine, Kanamycin, Capreomycin, Ethionamide, p-Amino-salicylic acid. Panel of drugs may vary.
Normals/Reference Interval: Control cultures - one strain that is sensitive to all of the drugs tested and one strain that has documented resistance to some of the drugs - are run with every batch of plate sens.
Cautions or Limitations: Requires sterile technique in a Level III Laboratory staffed by experienced Mycobacteriologists. Susceptibilities cannot be reported if the isolate fails to grow on the test media.
Reference:
1. Kent, P.T., Kubica, G.P., Public Health Mycobacteriology, A Guide for the Level III Laboratory, 1985, p.s. 159-184 Centers for Disease Control.
2. Heifers, LB. Drug susceptibility in the chemotherapy of mycobacterial infections. CBC Press 1991.
3. Murray, P.R. et. al. Manual of Clinical microbiology - 6th ed. ASM PRESS 1995.
4. Pierce, M., S.O.P. Mycobacteriology Lab. Manual - N.J. State Dept of Health. 1995.
5. ASTPHLD, C.D.C. Mycobacterium Tuberculosis: Assessing Your Laboratory March 1995.
Charge: $30

Inborn Errors of Metabolism Program

Serum T4

Synonyms: Thyroxine, serum (total)
Useful For: Monitoring treatment with synthetic hormones; confirming neonatal thyroxine screen.
Request Form: IEM-26
Specimen: Serum
Volume: 1 ml serum
Container: Red-top, non-heparinized tube
Collection: Collect 3 ml. of blood, allow blood to clot at room temperature, centrifuge and collect the serum. Serum should be separated within one hour after collection.
Storage Instructions: Frozen
Causes for Rejection: Lipemic and hemolyzed
Interpretation: <4.5 ug/dL considered low T4
Method: Radioimmunoassay
Normals/Reference Interval: Normal range 4.5-12.0 ug/dL
Cautions or Limitations: Conditions that may decrease total thyroxine are hereditary TBG deficiency, hypoproteinemia; drugs that may decrease total thyroxine are dilantin, salicylates, androgen administration, anabolic steroid administration.
Reference: Klein, A.H., Augustine, A.V., Foley, T.P. Successful laboratory Screening for congenital hypothyroidism. Lancet 1974;2:77-9.
Charge: No charge

Inborn Errors of Metabolism Program

Serum TSH

Synonyms: Thyroid stimulating hormone, serum
Useful For: Confirming neonatal TSH screen, diagnosis of primary congenital hypothyroidism.
Request Form: IEM-26
Specimen: Serum
Volume: 1 ml. serum
Container: Red-top, non-heparinized tube

Collection: Collect 3 ml. of blood, allow blood to clot at room temperature, centrifuge and collect the serum. Serum should be separated within one hour after collection.
Storage Instructions: Frozen
Causes for Rejection: Lipemic and hemolyzed
Interpretation: >9.0 uU/mL considered presumptive positive for hypothyroidism.
Method: Immunoradiometric assay or IRMA
Normals/Reference Interval: Normal range 0.54-3.70 uU/mL
Cautions or Limitations: Specimen collected at <24 hours of age may have elevated values.
Reference: Dubuis, J.M. and Burger, A.G., Thyroid Stimulating Hormone Measurements by Immuno-radiometric Assay in Severely Ill Patients, Lancet, II, 1036-1037, 1986.
Charge: No charge

Bacteriology
Shigella serotyping
Synonyms: Bacillary dysentery
Useful For: Determination of specific serotypes of Shigella, the geographic distribution and incidences of Shigella at the State and Federal level and monitoring of resistance patterns. Cultures are available for further studies such as PFGE and referral to the Centers for Disease Control.
Request Form: Bact. 109
Specimen: Pures cultures of Shigella on agar slants of appropriate media.
Volume: Viable colonies
Container: Agar slant with screw-cap mailed in container that conforms to US Postal regulations.
Collection: All Shigella isolates must be submitted to the laboratory as stated in New Jersey Administrative Code 8:57-1.
Storage Instructions: Maintain specimens at room temperature.
Causes for Rejection: Culture broken or destroyed in transit will not be processed.
Interpretation: There are four species of Shigella. Subgroup A (S. dysenteriae) is made up of organisms that do not use mannitol and do not bear close serologic relationships to the other subgroups. The Subgroup B (S. flexneri) contains six serotypes 1 through 6. Subgroup C contains serotypes of S. boydii and subgroup D contains only S. sonnei.
Method: Organism is grown on solid media then agglutinated on a slide for somatic antigens with specific antisera.
Normals/Reference Interval:
Cautions or Limitations: Both biochemical and serologic testing must be employed to characterize Shigella because of the close antigenic relationship of Shigella species to other organisms.
Reference: Ewing and Edwards, Identification of Enterobacteriaceae, 4th edition, New York, Elsevier Science Publishing Co., Inc. 1986.
Charge: No charge

Inborn Errors of Metabolism Program
Sickle Cell Family Testing
Synonyms: Isoelectric Focusing and HPLC
Useful For: Determining disease or trait state of sickle cell newborn's family.
Request Form: IEM-1a
Specimen: Blood
Volume: 100 ul/spot
Container: S&S #903 filter paper
Collection: Peripheral blood on S&S #903 filter paper (IEM-1a) and dried.
Storage Instructions: Cool, low humidity
Causes for Rejection: Specimen not on S&S #903 filter paper; specimen not attached to form; quantity blood insufficient; specimen contaminated or diluted; specimen over saturated; blood clotted or caked; filter paper torn or scratched; filter paper distorted; specimen received >14 days from collection date.
Interpretation: Specimens showing hemoglobin bands A, F, S, C, D, E, G, fast mover's and variants are reported.
Method: Isoelectric focusing and HPLC
Normals/Reference Interval: Normal newborns present adult and fetal hemoglobin bands; normal adults present hemoglobin A band; other bands indicate disease or trait(s).
Cautions or Limitations: Some hemoglobins which migrate to the same position by IEF cannot be distinguished; HPLC analyzes by area; some variant hemoglobin bands cannot be identified; results from patients who had blood transfusions are not valid.
Reference: Huisman, T.H.L. Separation of hemoglobins and hemoglobin chains by High Performance Liquid Chromatography. J. Chromatogr. 418:277, 1987.
Garrick, M.D., Dembure, P., Guthrie, R. Sickle-cell anemia and other hemoglobinopathies: procedures and strategy for screening spots of blood on filter paper as specimens. N. Engl J Med 288:1265, 1973.
Charge: $15/family (payable by money order or physicians office, hospital or clinic check; no personal checks)

Bacteriology
Standard Plate Count - Dairy Products
Note: Enforcement of State and Federal Regulations
Synonyms: SPC, Plate Count. Aerobic Plate Count
Useful For: Enumeration of total numbers of viable bacteria in dairy products. Indicator of sanitary quality of milk products. Enforcement of State and Federal Regulations.
Request Form: Bact. 10
Specimen: All uncultured dairy products.
Volume: Finished products - Volume N/A, Raw-100 ml.
Container: Finished products must be in the original sealed container. Raw samples must be submitted in single service containers.
Collection: By certified rating officers.
Storage Instructions: Samples must be transported and submitted at 0-4.4°C.
Cause for Rejection:
1. Leaking or unsterile containers.
2. Samples not transported and received at 0-4.4°C.
3. Sample exceeding time limit.
4. NO temperature control.

Interpretation: Excessive bacterial levels of raw samples are indicative of poor practices, unhealthy animals etc., postpasterurization contamination of finished products.
Method: Pour plate.
Normals/reference Interval: Refer to State Regulatory Agency.
Caution or Limitations: N/A
Reference: Standard Methods For the Examination of Dairy Products.
Charge: N/A-Enforcement Only.

Bacteriology

Standard Plate Count - Water Analysis

Synonyms: Total plate count, aerobic plate count

Useful For: Enumeration of total numbers of viable bacteria in potable water, usually bottle water, food and dairy products.

Request Form: Chem. 40 (water and food), Bact. 10 (dairy only)

Specimen: Potable water (bottled water, food and dairy products).

Volume: Food - minimum of 50 gms. Preferably 100 gms., Dairy - see section on SPC, dairy products, Water - minimum volume - 100 ml. Or unopened "Bottle Water".

Container: Water - 125 or 250 ml. Sterile bottles or single service containers supplied by NJDOH; Unopened "Bottle Water"; Food - "Sterile Whirl Bag" or other suitable sterile container. Dairy products - See section on SPC Dairy.

Collection: Refer to Standard Methods For the Examination of Water and Wastewater for proper sampling procedures. Food - Refer to Bacteriological Analytical Manual 7th Ed. Dairy - Refer to Standard Methods For the Examination of Dairy Products.

Storage Instructions: Transport and submit samples at 0-4.4°C. Water, excluding bottled water, submit samples within 30 hours.

Causes for Rejection:

1. Incorrect or outdated sample container.
2. Samples exceeding mandated transport time limits.
3. Samples not transported and received cold (0-4.4°C).
4. Food and dairy samples: Leaking containers.

Interpretation: Water - See Heterotopic Plate Count. Food - Elevated SPC indicates overall poor sanitary quality; handling practices, and/or inadequate cooking and refrigeration.

Method: Pour plate.

Normals/reference Interval: Refer to Drinking Water Regulations under the Safe Drinking Water Act, Criteria and Standards Division USEPA/Bathing and Surface Water Regulations, USEPA, Laws and Regulations Governing the Manufacturing, Storage, Distribution and Handling of Non-alcoholic Beverages and Bottled Water - NJDEPE.

Cautions or Limitations: Bacterial recovery rates in water, tend to be less than that of the HPC when used with the specified nutrient depleted media. The Standard Plate Count is a more useful indicator when applied to Food and Dairy products.

Reference: Standard Methods For the Examination of Water and Wastewater; Bacteriological Analytical Manual 7th Ed.

Charge: Water: Food: Dairy: N/A

Bacteriology

Stool Culture, Enteric Pathogens

Synonyms: Culture, Stool, Routine; Stool Culture, Comprehensive; Feces Culture

Useful For: Screen for bacterial pathogens in the stool, diagnose typhoid fever, enteric fever, bacillary dysentery, Salmonella/Shigella infection, Bacillus cereus, Clostridium perfringens and staphylococci food poisoning, Enterohemorrhagic E. coli (EHEC), Pleisiomonas shigelloides, Aeromonas hydrophila, Yersinia species, Vibrio species, and Campylobacter species.

Request Form: Bact. 25

Specimen: Stool

Volume: 25-50 grams of stool

Container: Blue labeled container or commercial collection kit.

Collection: Stool specimen should be collected into a clean dry container such as a newspaper, a plastic plate, a plastic bag, or a bedpan and not contaminated with urine, residual soap, disinfectant. Follow directions enclosed in specimen collection kit. VIBRIO AND CAMPYLOBACTER DIAGNOSIS REQUIRE THE USE OF A COMMERCIAL KIT.

Storage Instructions: Maintain specimens at room temperature. Refrigerate if delay in transport is expected.

Causes for Rejection: Specimen sent unpreserved; specimen leaked in transit.

Interpretation: In acute or subacute diarrhea, three common syndromes are recognized: gastroenteritis, enteritis, and colitis(dysenteric syndrome). With colitis, patients have fecal urgency and tenesmus. Stool is frequently small in volume and contain blood, mucus and leukocytes. Diarrhea of the small bowel is indicated by the passage of few large volume stools. This is due to an accumulation of fluid in the large bowel before passage. Bacterial diarrhea is transient (1 to 30 days) but cases of symptoms lasting 10 months have been reported.

Method: Aerobic culture on selective media.

Normals/Reference Interval: No enteric pathogens isolated.

Cautions or Limitations: Yersinia sp., Vibrio sp. and Campylobacter sp. require special media and have special growth requirements, the laboratory should be notified (609-292-7368) prior to submission of specimens.

Reference: Jacobs D, Demott W, et al, Laboratory Test Handbook 3rd edition Hudson, Ohio, Lexi-Comp Inc., 1994.

Charge: No Charge for specimens referred by the Division of Epidemiology or submitted through Local Health Departments. All others $30.

Syphilis Confirmatory Unit

Syphilis Serology, Fluorescent Treponemal Antibody Absorption Test

Synonyms: FTA-ABS

Useful For: Confirmation of Syphilis

Request Form: SER-2

Specimen: Serum

Volume: 1 ml

Container: Red Top Tube

Collection: Venipuncture

Storage Instructions: Refrigerate (2-8 Celsius degrees)

Causes for Rejection: Specimens are grossly contaminated, excessively hemolyzed or chylous.

Interpretation: A Reactive indicates antibody to T. pallidum; does not distinguish between current or past infection.

Method: Indirect Fluorescent Antibody (IFA)

Normals/Reference Interval: Nonreactive

Cautions or Limitations: Should not be used to follow disease activity or response to treatment since antibodies remain elevated for life. This test does not distinguish between syphilis, pinta, yaws and bejel. Biological false positives may occur.

Reference: Larsen, S.A., E.F. Hunter and S.T. Kraus (ed.) 1990. A Manuel of Tests for Syphilis, 8th ed. American Public Health Association, Washington, D.C.

Charge: $8 consultative fee.

Syphilis Confirmatory Unit

Syphilis Serology, Microhemagglutination - Treponema pallidum

Synonyms: MHA-TP
Useful For: Confirmation of syphilis
Request Form: SER-2
Specimen: Serum
Volume: l ml
Container: Red Top Tube
Collection: Venipuncture
Storage Instructions: Refrigerate (2-8 Celsius degrees)
Causes for Rejection: Specimens are grossly contaminated; excessively hemolyzed or chylous.
Interpretation: A Reactive indicates antibody to T. pallidum; does not distinguish between current or past infection.
Method: Hemagglutination
Normals/Reference Interval: Nonreactive
Cautions or Limitations: Less sensitive than FTA-ABS test in the detection of primary syphilis. This test is not recommended for cerebrospinal fluid testing or as a screening test for syphilis. Sera from patients with infectious mononucleosis, leprosy, drug addiction or autoimmune disease may cause false positive reactions.
Reference: Larsen, S.A., E.F. Hunter, and S.J. Kraus (ed.) 1990. A Manuel of Tests for Syphilis, 8th ed. American Public Health Association, Washington, D.C.
Charge: $8 consultative fee.

Syphilis Screening Unit

Syphilis Serology, Rapid Plasma Reagin Card Test

Synonyms: RPR Card Test
Useful For: The detection of antilipid antibodies (reagin) present in the serum or plasma of persons with syphilis.
Request Form: SER-1
Specimen: Serum or Plasma
Volume: 1 to 5 ml
Container: 13 x 100 or 16 x 100 Red Top Vacutainer tube with no preservatives.
Collection: Venipuncture
Storage Instructions: If testing is to be delayed more than 24 hours after collection, store at 2-8 Celsius degrees.
Causes for Rejection: Specimens are grossly contaminated, excessively hemolyzed or chylous.
Interpretation: The RPR card test is an aid in the diagnosis of syphilis. Without some other support for the diagnosis of syphilis, a reactive RPR card test is commonly unrelated to Treponema pallidum infection.
Method: Macro-flocculation
Normals/Reference Interval: Nonreactive
Cautions or Limitations: The RPR card tests cannot be used to test spinal fluids. The RPR card test may be reactive in persons from areas where yaws, pinta or nonvenereal syphilis is endemic. Biological false-positive (BFP) reactions occur occasionally with cardiolipin antigens, from persons who abuse drugs, who have diseases such as lupus erythematosus, mononucleosis, malaria, leprosy, or viral pneumonia; or who have been recently vaccinated, are pregnant, or are immuno-compromised.
Reference: Larsen, S.A., E.F. Hunter, and S.J. Kraus (ed.), 1990, A Manuel of Tests for Syphilis, 8th ed. American Public Health Association, Washington, D.C.
Charge: Call for pricing.

Syphilis Screening Unit

Syphilis Serology, Venereal Disease Research Laboratory Slide Test

Synonyms: VDRL Test
Useful For: The detection of antilipid antibodies (reagin) present in the cerebrospinal fluid of persons with syphilis.
Request Form: SER-2
Specimen: Cerebrospinal fluid
Volume: 1 to 3 ml
Container: 13 x 100 or 16 x 100 Red Top Vacutainer tube with no preservatives.
Collection: Spinal tap
Storage Instructions: If testing is to be delayed more than 24 hours after collection, store at 2-8 Celsius degrees.
Causes for Rejection: Specimens are visibly contaminated, or contain gross blood.
Interpretation: The VDRL test is an aid in the diagnosis of syphilis. A reactive VDRL test on CSF, free of blood or other contaminants, almost always indicates past or present syphilis infection of the central nervous system.
Method: Micro-flocculation
Normals/Reference Interval: Nonreactive
Cautions or Limitations: The VDRL-CSF test should be performed only when patient's serum treponemal test is reactive. The VDRL-CSF test may give biological false-positives in persons from areas where yaws, pinta or nonvenereal syphilis is endemic.
Reference: Larsen, S.A., E.F. Hunter, and S.J. Kraus (ed.), 1990, A Manuel of Tests for Syphilis, 8th ed. American Public Health Association, Washington, D.C.
Charge: Call for pricing.

Bacteriology

Throat Culture for Corynebacterium diphtheriae

Synonyms: Diphtheria culture, Corynebacterium diphtheriae culture
Useful For: Diagnosis of Diphtheria. Prior approval of the Division of Epidemiology (609-588-7500) is required before submission of specimens.
Request Form: Hospital laboratory form
Specimen: Throat swab, nasopharyngeal swab
Volume:
Container: Sterile Mini-tip Culturette(R) or flexible calcium alginate swab, Calgiswab(R) is recommended for obtaining nasophryngeal culture.
Collection: The tongue should be depressed while both the tonsillar crypts and nasopharnyx and throat lesions are swabbed. If a pseudomembrane is present, the swab should be taken from the membrane and beneath its edge if possible. Separate swabs for throat and nasopharnyx are desirable. Avoid swabbing the tongue and uvula. Specimen must be transported to the laboratory immediately following collection.
Storage Instructions: Refrigerate specimen if it cannot be delivered promptly.
Causes for Rejection: Negative results of specimens improperly stored will be qualified.

Interpretation: The organism is noninvasive, however, the exotoxin elaborated in the throat affects primarily the heart and nervous system. Mortality is 10% to 30%. Only strains infected by B-phage are capable of producing toxin. Nontoxigenic strains are commonly recovered and are capable of producing pharyngitis. Confirmation of exotoxin production requires animal testing.
Method: Culture on Loeffler's medium and cysteine tellurite agar. Smear stained with Loeffler's methylene blue stain and/or Gram stain. C. diphtheriae may appear as V, Y, of L figures. Metachromatic granules which stain deep blue may be seen.
Normals/Reference Interval: No C. diphtheriae isolated.
Cautions or Limitations: Contraindication: Lack of clinical symptoms or signs of diphtheria, valid history of immunization. C. ulcerans may also produce a diphteria-like disease.
Reference: Jacobs D., Demott W., et. al., Laboratory Test Handbook 3rd edition, Hudson, Ohio: Lexi-Comp Inc. 1994.
Charge: No charge

Bacteriology

Total Coliform - Dairy

Note: Enforcement of State and Federal Regulations
Synonyms: Coliform Count
Useful For: Enumeration of total coliforms in dairy products. Indicator of post pasteurization sanitary quality.
Request Form: Bact. 10
Specimen: All pasteurized dairy products.
Volume: N/A
Container: Original sealed container.
Collection: By certified rating officers.
Storage Instructions: Sample must be transported and submitted at 0.4.4°C.
Causes for Rejection:
1. Leaking or unsterile container.
2. Samples not transported and received at 0-4.4°C.
3. Samples exceeding time limit.
4. No temperature control.

Interpretation: Coliform counts above 10/ml. Are indicative of a "Below Standard" product.
Method: Pour plate
Normals/reference Interval: Must not exceed 10/ml.
Cautions or Limitations: N/A
Reference: Standard Methods For the Examination of Dairy Products.
Charge: N/A-Enforcement Only.

Bacteriology

Total Coliform - Water and Wastewater Analysis

Synonyms: Total Coliform MF; Total Coliform MPN
Useful For: Evaluating the quality of water for domestic, industrial and the effectiveness of treatment processes.
Note: Used in conjunction with Fecal Coliform analyses on all potable water samples.
Request Form: Bact. 52; Chem. 44; PW 2 or Chem. 40.
Specimen: Potable water and non-potable water.
Volume: Minimum volume 100 ml.
Container: 125 or 250 ml sterile bottles supplied by NJDOH.
Collection: Refer to Standard Methods For the Examination of Water and Wastewater for proper sampling procedures.
Storage Instructions: Maintain sample at 0-4.4°C. Submit potable water samples within 30 hours and non-potable water within 6 hours of collection.
Submit samples to Room 237, ECLIS, State Health Department Laboratory Building.
Useful For: Determining the T. gondii specific antibodies in serum or plasma. May be used to assess immune status with a single specimen or as a diagnostic test using acute and convalescent sera.
Cause for Rejection:
1. Incorrect or outdated sample container.
2. Samples exceeding mandated transport - time limits.
3. Samples not transported and received cold. Preferably at 0-4.4°C.

Interpretation: When combined with engineering or sanitary surveys, provides a good assessment of water treatment effectiveness and sanitary quality of untreated water.
Method: Membrane Filter or Multiple Tube Fermentation Method (MPN).
Normals/reference Interval: Refer to Drinking Water Regulations under the Safe Drinking Water Act Criteria and Standards Division USEPA/Bathing and Surface Water Regulations, NJDEPE.
Cautions or Limitations: The total coliform test can be used for any type of water or wastewater, however, it is best used as an indicator of bacteriological quality for potable water, distribution systems and public supplies. It should not be used only but rather in conjunction with other indicators to determine fecal contamination. Use Membrane Filter Method for potable water and the multiple tube fermentation method (MPN) for very turbid or non-potable water samples.
Reference: Standard Methods For the Examination of Water and Wastewater. Microbiological Methods for Monitoring the Environment.
Charge: Membrane Filter $15 inc. (Fecal Coliform) Multiple Tube Fermentation (MPN) $13.

Bacteriology

Total Coliforms/Fecal Coliforms - Food Analysis

Synonyms: "Coliform" analysis
Useful For: The enumeration of total and fecal coliforms in food.
Request Form: Chem. 40
Specimen: Any food sample.
Volume: Minimum of 50 gms; 100 gms. preferable.
Container: Sterile plastic container.
Collection: Refer to Bacteriological Analytical Manual 7th Ed.
Storage Instruction: Transport and submit samples at 0-4.4°C.
Causes for Rejection:
1. Leaking or unsterile containers.
2. Samples not transported and received cold, 0-4.4°C.

Interpretation: Total and fecal coliforms should be examined in conjunction with one another. High levels of these coliforms are indicative of unsanitary practices and contamination.
Method: Multiple Tube Fermentation Method (MPN).
Normal/reference Interval: Fecal coliforms not present.
Cautions or Limitations: MPN Procedure is not an exact enumeration but a value derived statistically.
Reference: Bacteriological Analytical Manual 7th Ed.
Charge: N/A

Viral Serology

Toxoplasmosis - FIA

Synonyms: Toxoplasma gondii, fluorometric immunoassay

Request Form: SER-1
Specimen: Serum or plasma
Volume: 2-5 ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture. Paired specimens must be assayed together. Acute serum is collected within 7 days of onset and a convalescent specimen is collected at least 10 days later.
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of > 1:16 is considered reactive. An increase in titer between acute and convalescent specimens by a factor of 3.0 is indicative of a current infection.
Method: Fluorometric immunoassay
Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.
Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Viral Serology
Toxoplasmosis M - FIA
Synonyms: Toxoplasma gondii, IgM fluorometric immunoassay
Useful For: Determining the T. gondii IgM specific antibodies in serum or plasma. May be used to assess immune status with a single specimen.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 2-5 ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of > 1:10 is considered indicative of a current infection.
Method: Fluorometric immunoassay
Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.
Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Special Immunology
Trichinosis Serology
Synonyms: Trichinella Antibodies
Useful For: Screen for Antibodies to Trichinella spiralis Antibodies.
Request Form: SRD-1
Specimen: Serum
Volume: 3 ml
Container: Red top tube
Collection: A second specimen drawn 2-4 weeks after the first might prove more informative than a single serum.
Storage Instructions: Refrigerate
Causes for Rejection: Gross bacterial contamination.
Interpretation: Titers of ≥ 1:5 are considered diagnostic of Trichinella infection.
Method: Bentonite flocculation test (BFT)
Normals/Reference Interval: Negative: Titer <1:5
Cautions or Limitations: Low titers may represent antibody from previous rather than current infection.
Reference:
1. Bruschi F, Tassi C, and Pozio E, "Parasite-Specific Antibody Response in Trichinella sp Human Infection: A One Year Follow-up", Am J Trop Med Hyg; 1990 43(2):186:93.
2. Kagan IG and Maddison SE, "Serodiagnosis of Parasite Diseases", Manual of Clinical Laboratory Immunology, 4th ed. vol. 2, Chapter 79, Rose NR, Conway de Macario E, Fahey JL, et al, eds. Washington, DC: American Society for Microbiology, 1992, 529-43.
3. Orihel TC and Ash LR, "Tissue Helminths", Manual of Clinical Microbiology, 4th ed. Balows A, Hausler WJ Jr, Shadomy HJ, et al, eds. Washington, DC: American Society for Microbiology, 1985, 651-59.

Charge: None

Special Immunology
Tularemia Agglutinins
Synonyms: Francisella tularensis Antibodies, Rabbit Fever Antibodies
Useful For: Diagnosis of Tularemia
Request Form: SRD-1
Specimen: Serum
Volume: 3 ml
Container: Red top tube
Collection: Acute and convalescent sera, collected 7-10 days later, are recommended.
Storage Instructions: Refrigerate
Causes for Rejection:
Interpretation: Titers of ≥ 1:40 are diagnostically significant and may indicate previous or current infection. Rising titers on successive specimens gives diagnostic assurance of a current infection.
Method: Tube agglutination
Normals/Reference Interval: Agglutination titer <1:40
Cautions or Limitations: Cross reactions with Brucella, Proteus OX-19. Titers remain elevated for years after exposure; single titers may be misleading.

Reference:
1. Hovnick RB, "Tularemia", Cecil Textbook of Medicine, 19th ed, Wyngaarden JB, Smith LH Jr, and Bennett JC, eds, Philadelphia, PA: WB Saunders Co, 1992, 1712-14
2. Stewart SJ, "Francisella", Manual of Clinical Microbiology, 5th ed, Chapter 43, Balows A, Hausler WJ Jr, Herrmann KL, et al, eds, Washington, DC: American Society for Microbiology, 1991, 360-3
Charge: None

Viral Serology

Varicella/Zoster - FIA

Synonyms: VZV, fluorometric immunoassay, chicken pox, herpes zoster, shingles

Useful For: Determining the VZV specific antibodies in serum or plasma. May be used to assess immune status with a single specimen or as a diagnostic test using acute and convalescent sera.
Request Form: SRD-1
Specimen: Serum or plasma
Volume: 2-5 ml
Container: Vacutainer (red, brown or violet top)
Collection: Venipuncture. Paired specimens must be assayed together. Acute serum is collected within 7 days of onset and a convalescent specimen is collected at least 10 days later.
Storage Instructions: Specimens should be stored at 4°C for up to 7 days, longer storage requires cell separation and freezing at -20°C.
Causes for Rejection: Breakage, leakage or insufficient quantity for testing.
Interpretation: A calibration curve is constructed using kit reagents and specimen titers are interpolated from the curve. A single serum titer of > 1:8 is considered reactive. An increase in titer between acute and convalescent specimens by a factor of 2.0 is indicative of a current infection.
Method: Fluorometric immunoassay
Normals/Reference Interval: Kit calibrators and controls must be within assay parameters when constructing the titer interpolation curve.
Cautions or Limitations: The test is limited in its ability to compare with the manufacturers performance characteristics when instrument, protocol, reagent and sample recommendations are not followed.
Reference: "Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections; 6th Ed.; Schmidt, N.J., and R.W. Emmons. APHA; 1989.
Charge: $10

Diagnostic Virology

Varicella Zoster Virus Isolation

Synonyms: VZV, chicken pox, shingles

Useful For: Determining the etiology of a suspected viral infection.
Request Form: SRD-1
Specimen: Lesion swabs, vesicle fluid.
Volume: Lesion swab in 2.0ml, 0.5% gelatin saline solution or culturette. Vesicle fluid in 1.0ml, 0.5% gelatin saline solution, using tuberculin syringe.
Container: Swabs in sterile screw cap tube. Vesicle fluid expressed into sterile screw cap tube.
Collection: Specimens should be collected when lesions are vesicular.
Storage Instructions: Specimens should be stored at 4°C and delivered to the laboratory within 24hrs of collection.
Causes for Rejection: Breakage, leakage of specimen containers or obvious bacterial contamination will be cause for rejection.
Interpretation: The presence of a slowly progressive, focal, cytopathogenic effect (CPE) is indicative of viral isolation.
Method: Inoculation in tissue culture.
Normals/Reference Interval: Failure to see CPE in tissue culture after one 21 day incubation period.
Cautions or Limitations: Failure to isolate a virus does not rule out the possibility of a viral infection.
Reference: Lennette, E.H. and N.J. Schmidt."Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections", 6th Edition, American Public Health Association, Washington, DC.
Charge: None

ECLS-Biochemistry

Zinc Protoporphyrin (with Childhood Lead Confirmation)

Synonyms: ZnPP, ZP, EP, Lead and EP

Useful For: Anemia, incidence of lead poisoning, differentiating microcyctic anemia from thalassemia and other globin-synthesis disorders in pediatric cases.
Request Form: CHEM-26
Specimen: Whole Blood
Volume: 1.0mL
Container: Tan top vacutainer, lead-free, sodium heparin (protect from light)
Collection/Preservation: Mix well after collection to minimize clotting
Storage Instructions: Refrigerate, protect from light
Causes for Rejection: Clotted specimen, insufficient sample volume
Interpretation: Values of zinc-complexed protoporphyrin >35*u*g/dL suggest lead exposure. Elevated results may also indicate certain anemias or iron deficiency.
Method: Fluorometry
Normal/Reference Interval: Normal ZPP 0 to 35*u*g/dL
Cautions or Limitations: Fluorescent substances in plasma may interfere with hematofluorometer results.
Reference: Erythrocyte ZnPP in Diagnosing Iron Depletion, Diana S. Trundle, Ph.D., et al, Laboratory Management, July 1985; "Evaluation of the erythrocyte protoporphyrin test as a screen for elevated blood lead levels", Michael D. McElvaine, DVM, MPH, et al, The Journal of Pediatrics, October 1991.
Charge: $12 (includes blood lead level)

ECLS-Biochemistry

Zinc Protoporphyrin (with Lead Confirmation) Occupational Exposure

Synonyms: ZnPP, ZP, EP, Lead and EP

Useful For: Anemia, incidence of lead poisoning, differentiating microcyctic anemia from thalassemia and other globin-synthesis disorders in occupational exposure.
Request Form: CHEM-26
Specimen: Whole Blood
Volume: 1.0mL
Container: Tan top vacutainer, lead-free, sodium heparin (protect from light)

Collection/Preservation: Mix well after collection to minimize clotting
Storage Instructions: Refrigerate, protect from light
Causes for Rejection: Clotted specimen, insufficient sample volume
Interpretation: Values of zinc-complexed protoporphyrin >100*u*g/dL suggest lead exposure. Elevated results may also indicate certain anemias or iron deficiency.
Method: Fluorometry
Normal/Reference Interval: Normal ZPP 0 to 70*u*g/dL
Cautions or Limitations: Fluorescent substances in plasma may interfere with hematofluorometer results.
Reference: Biological Exposure Indices (BEI) based on the 1993-4 recommendations of the American Conference of Governmental Industrial Hygienists (ACHGIH); Erythrocyte ZnPP in Diagnosing Iron Depletion, Diana S. Trundle, Ph.D., et al, Laboratory Management, July 1985.
Charge: $12 (includes blood lead level)

ECLS-Biochemistry

Zinc Protoporphyrin (with Lead Screening)

Synonyms: ZnPP, ZP, EP, Lead and EP
Useful For: Anemia, incidence of lead poisoning, differentiating microcyctic anemia from thalassemia and other globin-synthesis disorders.
Request Form: CHEM-26
Specimen: Whole Blood
Volume: 500*u*L
Container: Sarstedt microvette, CB1000, amber with green top, ammonium heparin
Collection/Preservation: Mix well after collection to minimize clotting
Storage Instructions: Refrigerate
Causes for Rejection: Clotted specimen, insufficient sample volume
Interpretation: Values of zinc-complexed protoporphyrin >60*u*g/dL suggest lead exposure. Elevated results may also indicate certain anemias or iron deficiency.
Method: Fluorometry
Normal/Reference Interval: Normal ZPP 0 to 35ug/dL
Cautions or Limitations: Fluorescent substances in plasma may interfere with hematofluorometer results.
Reference: "Erythrocyte ZnPP in Diagnosing Iron Depletion", Diana S. Trundle, Ph.D., et al, Laboratory Management, July 1985; "Evaluation of the erythrocyte protoporphyrin test as a screen for elevated blood lead levels", D. McElvaine, DVM, MPH, et al, The Journal of Pediatrics, October 1991.
Charge: $12 (includes blood lead level)